# “OGB PolyTrend”
# (8070)
# Intensive Care Incubator
# User Manual

*THIS MANUAL HAS BEEN PRODUCED*
*RESPECTING THE CURRENT STANDARDS.*

**This manual refers to the enclosed equipment:**

**"OGB Polytrend"** ***INCUBATOR***

S/N: _____

# 1. PRESENTATION

## Presentation

*Dear Customer*
*Ginevri thanks you for choosing our firm and the quality of our products. The longstanding Ginevri traditions of professionalism, reliability and availability will once again prove to be your best reward for entrusting us at Ginevri with your neonatal purchases.*

*Giorgio Ginevri*

**GINEVRI s.r.l. – Registered office**

Via Cancelliera 25/B - 00041 - Albano Laziale (Roma) - Italy

**Warning**

This manual must be carefully read by all personnel who install, use or maintain these units.

The operation of this equipment in accordance with the instructions contained in the user and service manuals, combined with regular service maintenance - performed with Ginevri original spare parts and consumables - will assure the efficiency of our devices and the long lasting quality of their performance and reliability.

Maintenance and service must only be performed by technicians who have been trained and authorized by Ginevri.

## Maintenance service

Ginevri representative in your country can stipulate, within one month before warranty period expiry, various kinds of maintenance contract.

For any inquiry please contact us:

**GINEVRI s.r.l.** - Servizio Assistenza Clienti
Via Cancelliera 25/B
00041 Albano Laziale (Roma) - Italy
tel. 06 93459331
fax 06 93459393
E-mail: **export@ginevri.com**
www.ginevri.com

The device is manufactured in compliance with the standards CEI 62.5 (file 1445 of 01/91) and EN 60 601-1 and related IEC 601-2-50. Moreover the device is provided with an EMC (electromagnetic compatibility) anti-jamming device.

If servicing/maintenance after warranty period is performed by other companies not qualified/authorized by us, all fixed parts have to be marked by the repairer. The repairer has to verify and guarantee in writing the perfect functioning of the device. Any modification of the device must comply with the Medical Devices Normative law 93/42/CEE and approved by Ginevri s.r.l.

For maintenance service original materials must be used.

# 2. "EC" CERTIFICATE

## "EC" Certificate

EC CERTIFICATE

Certificate No 747/MDD

Annex

**Infant intensive care incubators**
Type ref. OGB Poly Care 1; OGB Poly Care 2; OGB Poly Care 3; OGB Poly Care 4; OGB polytrend.
Trade mark Ginevri

**Transport infant incubators**
Type ref. Baby Shuttle Normal Care; Baby Shuttle Special Care; Baby Shuttle Intensive Care.
Trade mark Ginevri

**Infant warmers**
Type ref. IW409; IW509; IW909.
Trade mark Ginevri

Series: IW509 PLUS.
Trade mark Ginevri

Series: Isola Neonatale Type ref. ALHENA PLUS ELEVABILE; ALHENA PLUS FISSA; ALHENA ELEVABILE; ALHENA FISSA.
Trade mark Ginevri

**Infant heating mattress**
Type ref. Acquatherm.
Trade mark Ginevri

**Oxygen analyzers**
Type ref. LCD 1000.
Trade mark Ginevri

**Oxygen tents**
Type ref. Oxytent 1000; Oxytent 2000.
Trade mark Ginevri

**Phototherapy lamps in neonatal hyperbilirubinemia**
Type ref. IP; IPR; RPR; RPS; D; GN; Billilight.
Trade mark Ginevri

**Auxiliary infant warmers**
Type ref. Hot Spot.
Trade mark Ginevri

**Air compressor for transport incubator**

Date: 2004-04-21
Updated: 2009-11-09
Substitution Date: 2009-04-17

IMQ

This is a translation of the Italian text, which prevails in case of doubts

IMQ

## "ISO" Certificates

UNI EN ISO 9001 - *Quality management system*
CSQ No. Cert. 9120.GIN1
IQnet No. Cert. IT-37100

CE 0051

UNI EN ISO 13485 - *Particular requirements for medical devices*
CSQ No. Cert. 9124.GIN2

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# 3. WARNINGS

The Incubator must only be used by qualified personnel, specifically trained and under the supervision of qualified medical staff conscious of all the benefits and risks involved with the use of the incubator itself. Notwithstanding that, we still recommend the following precautions:

## 3.1 USE PRECAUTIONS

- Direct sunlight and other types of radiant heat (heaters, phototherapy lamps, radiators, etc.) can raise the Incubator's internal temperature - **be careful**. The Incubator is equipped with both visual and acoustic alarms (HIGH TEMP, MAX TEMP) to alert staff to this problem.

- The use of oxygen raises the risk of fire. Do not introduce into the interior of the incubator accessories which could produce sparks. Small quantities of flammable agents such as alcohol and ether in the presence of oxygen can cause fires.

- When oxygen is administered you must you an analyser to check the oxygen percentage of the oxygen in the air mix. The introduction of oxygen with or without using a micro-climate cap can increase the internal noise level (dB) of the incubator.

- The temperature probe for taking the patient's skin temperature must be positioned in contact with the baby's skin onto the abdomen, **precisely between the belly button and the abdomen itself**.

  For a correct and secure attachment we recommend the use of our probe fixer gel(P/N 565);

- The temperature probe for measuring skin temperature must not be used as a rectal sensor

- Maximum attention must be given to make sure that other electrical equipment attached to the baby or positioned near the incubator conform to European Safety Standards and those relating to electromagnetic compatibility.

- Incorrect use of the incubator could be dangerous to the patient. The incubator must only be used by properly personal trained and under the supervision of Doctors aware of the risks and benefits involved.

- Make sure that the electrical wiring of the power supply has been installed and is maintained to the level prescribed by the European Standards.

- Before putting the little patient in the incubator**, make sure the incubator and its related accessories have been thoroughly cleaned, disinfected and that the equipment is in good working order (for this please see the Maintenance and Service Manual)**

- When for whatever reason **the control panel has to be taken out of the incubator base take maximum care with the resistance spiral because it could be hotter to the touch**.

- **The Incubator must only be unplugged from the main power supply after it has been switched off. A strict preventative maintenance programme is recommended in conjunction with very thorough and complete cleaning and disinfection of the incubator always strictly following the manufacturer's recommendations and frequency.**

- The incubator incorporates, for the micro-climate circulation; an electrical induction motor particularly **quiet: 45 dB inside the hood.** Wear and tear on the motor arm bushings, after approximately 5000 hours of use, can cause an increase in internal noise levels. **It is therefore recommended that the internal noise level of the incubator is periodically tested to make sure they stay inside the safety levels** and forewarn when the motor needs to be replaced when that level has been reached.

- Take care when closing the access doors of the hood to make sure that they are inserted into their holders.

- **For safety and security do not leave the baby unattended when the access door is open.**

- Two people, fairly strong, are needed to lift the incubator.

- **A pre-heating regime of approx. 30 minutes is needed when the incubator is first turned on before use.** Therefore, a good and safe standard procedure **is to wait until the internal temperature of the incubator has stabilized at the desired level before putting the patient inside.**

- Upon Switching On the Mute and Air/Skin buttons must be kept pressed simultaneously for the default setting of the oxygen, temperature and humidity to be memorized in the non-volatile memory.
- **The micro-filter,** which is highly efficient and is positioned in the tubing system for air taken in from outside, **must be kept clean.** It's substitution is recommended at least once per month. **However, a good standard practice is to change it for every patient.**

## 3.2 ELECTRICAL AND AGAINST EXPLOSIONS PRECAUTIONS

**Check the Earth.** Connect the AC power supply connector only to a 3 pin hospital standard socket. **Do not use extension leads. If there are any doubts about the earthing do not turn the equipment on.**

**If the Control Panel is opened, be careful because there is a risk of electrical shock inside the panel itself.**

**Maintenance must only be carried out by qualified personnel. Make sure the electrical power supply level is compatible with the electrical specifications displayed on the incubator label.**

Do not use the incubator in the presence of inflammable anaesthetics.
Make sure the incubator's oxygen flow is disconnected when it is being cleaning or having maintenance carried out because there is a risk of explosion when cleaning and maintenance operations are carried out in an oxygen rich environment.
**Lighting cigarettes and all other potential causes of fire must be eliminated from where the incubator is used. Fabrics, oils and other combustible materials are easily inflammable and burn with a great intensity in an oxygen rich atmosphere.**

# 4. GENERALITY

The philosophy which has guided Ginevri in the design of its equipment over more than 40 years of manufacture has always been the same:

**The use of modern advanced techniques coupled with extreme simplicity of use, cleaning and sterilization**.

**This philosophy has lead to the OGB PolyTrend line of Incubators.**

The ***OGB POLYTREND*** incubators are controlled by a micro-processor system which checks, monitors, and visualizes all the parameters and functions necessary in order to create an ideal micro-climate for the premature baby.

According to the version of the OGB PolyTrend selected, it is possible to regulate and check the following parameters:

- Air and Cutaneous Temperature (Air, Skin), with servo-controlled and proportional heating systems.
- Humidity, servo-controlled, and with an integrated system for the generation of sterile humidity.;
- Oxygen concentration inside the hood or head box – servo-controlled

**The setting of the parameters is done thru the use of "soft-touch" buttons and an "encoder" arranged in an easy to use error free fashion.**

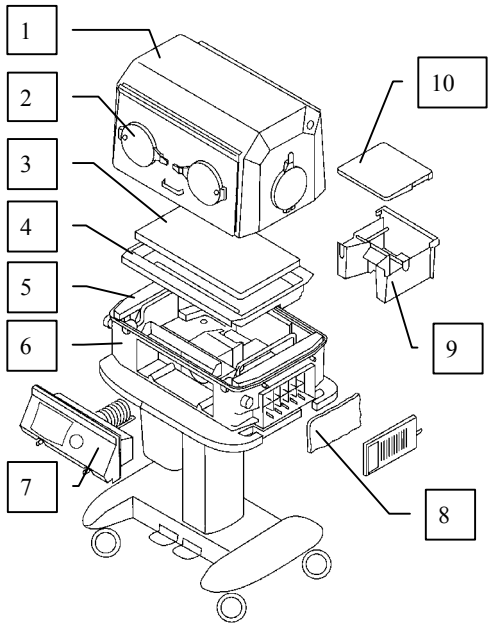
**On request, it is possible to connect to a Local Area Network and monitor, with a remote system, an unlimited number of incubators.**

The intensive care incubators can be equipped with a **radiant heat Hot Spot** which not only allows the maintenance of a **constant skin temperature of the patient even with the incubator doors open, but also makes superfluous the use of a double hood and/or a thermal hot air barrier.**

## *4.1 INTRODUTION*

The **OGB PolyTrend Incubator** with its micro-processor control system can work to control the heating level of both the air inside the incubator hood as well as the baby's temperature. Thanks to a proportional heating system the heat supplied varies directly in conjunction with the requested requirements. This system allows for the newborn baby's skin temperature to be stabilized with very small variations of the incubator internal temperature.

The diagram shows the various individual parts of the **OGB PolyTrend** supported on a wheeled cabinet:




1. Hood;
2. Porthole with sleeve and door
3. Fire-retardant mattress;
4. Patient tray equipped with a tilting bed system for the Trendelemburg and Fowler positions;
5. Sidebar with vent slits;
6. Base;
7. Control Panel;
8. Air Micro-filter (filters to less than 0.5micron);
9. Polycarbonate Humidifier reservoir;
10. Top part of the humidifier

All the above listed components are made of pressure fusion polycarbonate.

The **OGB PolyTrend** Incubator requires an electrical supply of 220V 50/60Hz 430W (570W with Hot Spot).

The proportional thermo-regulation system allows:

- Automatic and precision temperature regulation of the internal incubator hood temperature in order that the patient is warmed to and kept at the pre-selected patient skin temperature
- To keep the temperature always under control with pre-fixed high and low temperature alarms.
- Maintenance of a truly uniform internal hood temperature.
- To evaluate when it is possible to terminate the newborn baby's stay inside the incubator. As when:
  - The absence of heating (the heating element is turned off)
  - The internal hood temperature is equal to the ambient temperature;
  - The patient's temperature is at the pre-determined level;
  - Indicating that the newborn is self-sufficient for maintaining its own body temperature.

**The oxygen servo-control system (when needed) allows** the direct connection of the incubator to medical oxygen valves (both central supply system or bottle supply) **to select and maintain concentrations from 21% to 65% inside the hood and up to 100% in a head box micro-climate.**

**Thanks to the use of a special control algorithm, the concentration is maintained constant at the desired level even with the opening of the hood access ports or with small variable loses over time.**

**The OGB PolyTrend Incubator is equipped with the *Servo-Steam* Humidifier (when requested).**
With the ***Servo-Steam*** it is possible to select and servo-control the internal humidity level inside the hood **up to a value of 100%.**

**The humidity generation systems guarantees:**

- **Absolute sterility because the vaporizer connected to the compartment of the standard humidifier is isolated from the patient environment and works at 135°C;**
- **The water reservoir is placed on the exterior of the incubator;**
- **Only vapour enters and is diffused into the patient ambient.**

## 4.2 TECNOLOGY AND MATERIALS

What distinguishes the new generation of Incubators is the choice of materials and the new technologies used in their development and design.

The hood, the base, the command panel, the humidifier, the Smooth Tilt, the patient basin, as well as other minor components, are all made of polycarbonate (lexan), using one-piece hot pressure injection system moulds.

The sum total of the design, the shapes, the materials used, and how they are made is one of the many characteristics which distinguish the OGB PolyTrend incubators making them unique on the world market. In fact, no other make of equipment exists that offers, simultaneously, all these innovative functions.

The single piece stamping of the polycarbonate components, the rounded corners, and the absence of glued joints improves the air circulation, reduces internal noise and allows for very thorough cleaning, thus guaranteeing maximum reliability and performance from every point of view.

The technology used in the OGB PolyTrend makes repair and maintenance operations both simple and economic. From whatever corner of the world all that is needed is a FAX with a part number to obtain any spare part.

In fact, by working with stamped mechanical components - which guarantees the absolute repeatability for re-making those components - as well as the use of digital electronics allows for repairs to be done with the simple substitution of a board or a probe.

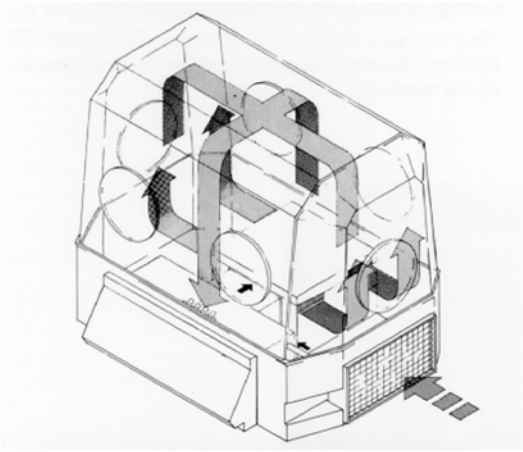
Polycarbonate is an unbreakable material which is resistant to high temperature (over 150°C), fire retardant and resistant to oils, fats, acids and normal disinfectants as well as other chemical agents.

The technology used in the construction of the OGB PolyTrend Incubators allows for complete dismantling, by hand without need for tools, of the entire machine within just a few minutes.

In fact, the use of one piece pressure injection polycarbonate for various components grants extreme manoeuvrability of the individual unit pieces for perfect cleaning and sterilization in conjunction with the absence of build-up of dirt, spore, etc.
The two access doors open upwards in order to avoid cross infection. These doors can also be open at the same time and the anchorage system allows the top of the hood to remain free.

The special pivot hinge is easily dismantled for complete sterilization and is silenced because of an in-built silicon component.

# 5. OPERATION



The external ambient air, enriched with oxygen if there is the need, enters into the incubator by passing through a high capacity micro-filter (less than 0.5 μm) located on the base.

A special fan sucks in the air from outside (with oxygen if necessary), it pushes into the heating chamber and after that to be passed through the flow, through the specially provided slits in the patient tray and the side holding bars. Through the specially designed slits of the patient basin and the side vent bars, into the hood without creating damaging turbulence around the newborn.

The circulation system forced by the internal micro-climate of the cockpit guarantees a constant air exchange (36 l/min.)[1].

The light "Venturi" effect which is created in the four sides of the hood near the centre of the hood guarantees, in addition to the elimination of $CO_2$ , the silent and uniform distribution of the micro-climate around the newborn.

**ATTENTION**

Check that the specially provided slits in the patient tray and the side holding are not obstructed, because in that condition an inadequate air circulation will result with the consequent increase in $CO_2$ level.

Keep the airway channels inside the incubator UNOBSTRUCTED, which guarantees not only uniform air circulation but, consequently, also temperature uniformity.

## 5.1 CONTROL PANEL

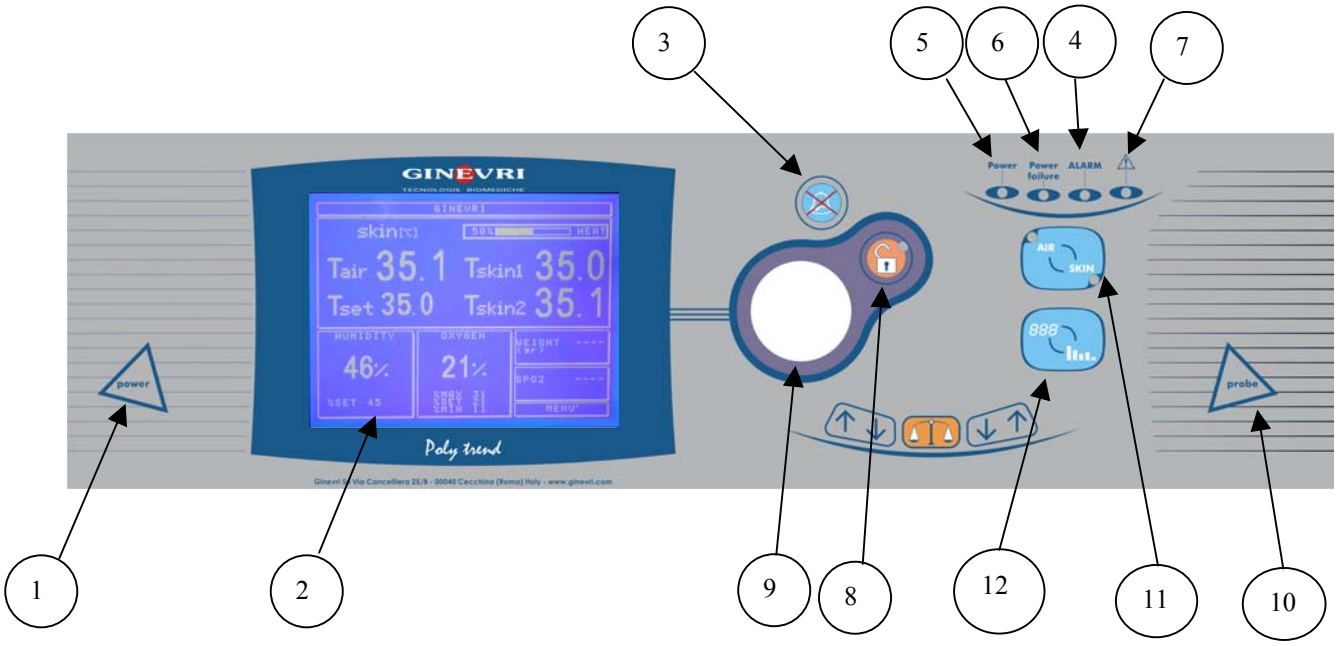



FIGURE (CONTROL PANEL)

1) **Power** button, located on the left side of the control panel with a warning light: if the switch is pressed without a power supply the Power Failure Alarm will sound. On the switch/filter block you find the electrical supply wire and the machine's two protection fuses.
2) **Liquid crystal display** (LCD), on which the various values taken from the incubator's sensors are seen as well as the control alarms.
3) **Mute** button, when pressed this silences the sounding alarms for approx. 15min.
4) **Alarm,** red LED, the LED lights up with the activation of any alarm. If the alarm is muted the LED continues to flash, until the acoustic alarm comes back on by itself after 15 min, the LED turns itself back on without flashing.
5) **Power**, **green** LED , lights up when there is a power supply turned on.
6) **Power Failure**, red LED, lack of power alarm which activates in case of lack of 220V power supply.
7) ⚠, **orange LED**, this LED turns on when the selected temperature is above 37°C or the selected oxygen concentration is above 40%.
8) **Block** button with **LED light**, this button is used to enable or disable the encoder, with the accompanying turning on or turning off of the LED.
9) **Encoder**, is used to set the control parameters and to move between the various display screens.
10) Probe, **connectors** for the probe assembly**,** of the *Servo-Steam* and for the oxygen supply, positioned on the right side of the control panel.
11) **AIR/SKIN button** with two **LED lamps**, which when pressed permits the change of the size which is being thermo-regulated, with the consequent lighting of the LED in the selection area.
12) **Digital Trend Button**, when pressed permits the instantaneous transfer from the Numerical Data screen to the Temperature Trend screen.

## 5.2 MANAGEMENT OF THE DIFFERENT VISUAL DISPLAYS

The Incubator is managed by using and setting different visual display screens. From the initial numeric data display screen, which shows the data readings, it is possible to access all the other displays using the "Display Menu".

To access the display screens after the numeric data display, proceed as follows:

1. Press the Block button (8) if the encoder is blocked, with the corresponding LED switching off.
2. Turn the encoder until the menu field on the numeric data screen is selected.
3. Press the encoder to activate the "Menu Display". A list of the new displays available will be shown.
4. Turn the encoder to select the desired display screen. The selected field will flash.
5. Press the encoder to access the desired display screen.

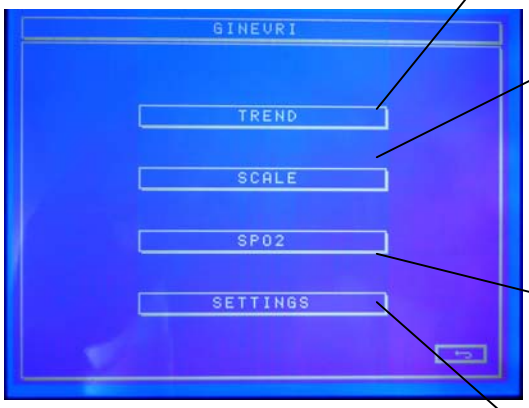
The display screen selection procedure is the same for the selection of any of the other display screens as for example the "Trend Display" or the "Settings Display" from which new setting functions can be accessed. The procedure to follow will always be the same as that listed above.

NUMERIC DATA DISPLAY SCREEN

FIGURE (NUMERIC DATA DISPLAY SCREEN)

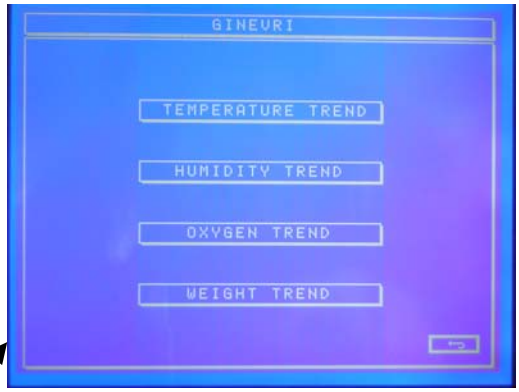
- **Tair**, incubator internal air temperature
- **Tskin1**, patient skin temperature (to check);
- **Tskin2**, patient skin temperature (peripheral).
- **Tset,** pre-set temperature for air or skin thermo-regulation
- **HEAT**, heating percentage (Numeric value and bar graphic)
- **HUMIDITY**, humidity percentage reading inside the hood.
- **%SET**, pre-set humidity percentage.
- **OXYGEN**, oxygen percentage
- **%SET**, pre-set oxygen percentage.
- **%MAX**, maximum limit for oxygen percentage without alarm activation
- **%MIN**, minimum limit for oxygen percentage without alarm activation
- **WEIGHT**, weight in grams
- **SPO2**, blood oxygen percentage level.
- **MENU**, area used to activate the Menu display.
- **>37°C**, when the pre-set temperature is greater than 37 °C.
- **>40%,** when the pre-set oxygen level is greater than 40%.

**ALARMS**, area reserved for the description of activated alarms which will appear in the upper area of the screen in place of the GINEVRI name.



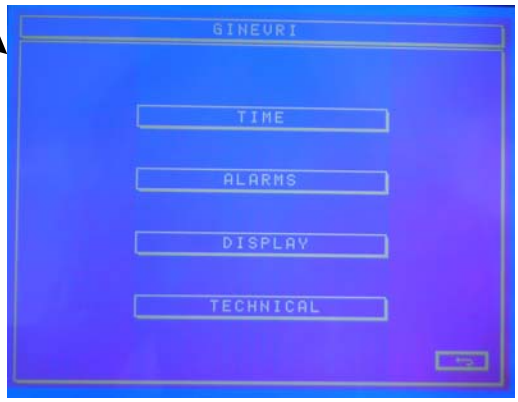

(DISPLAY MENU)

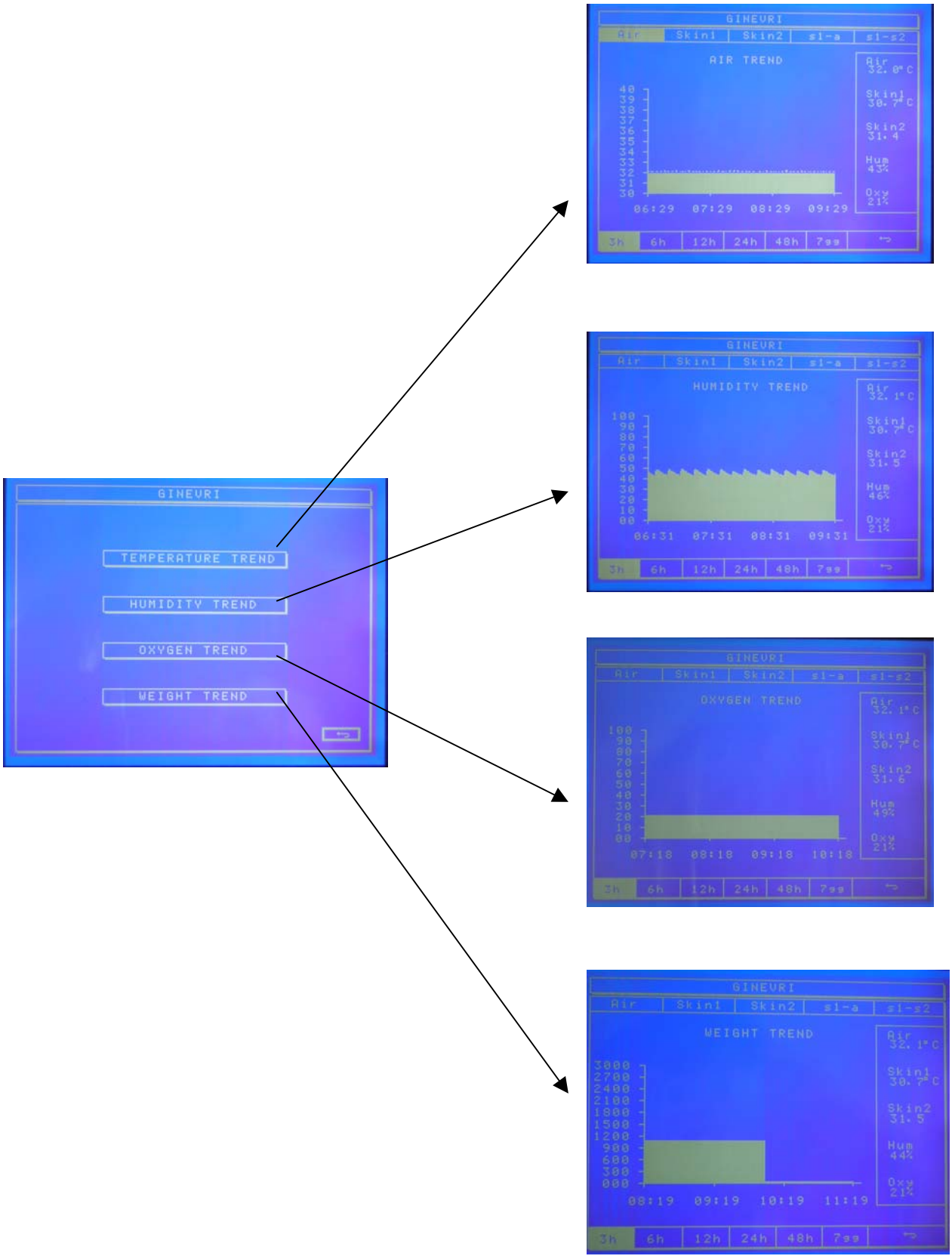
- **TREND,** active area to access the Trends
- **SCALE,** active area to access the Scales Display
- **$SpO_2$,** active area to access the Pulse Oxymeter Display
- **SETTINGS,** active are to access the Settings
- ↵ **"return**", return to the Numeric Data Display

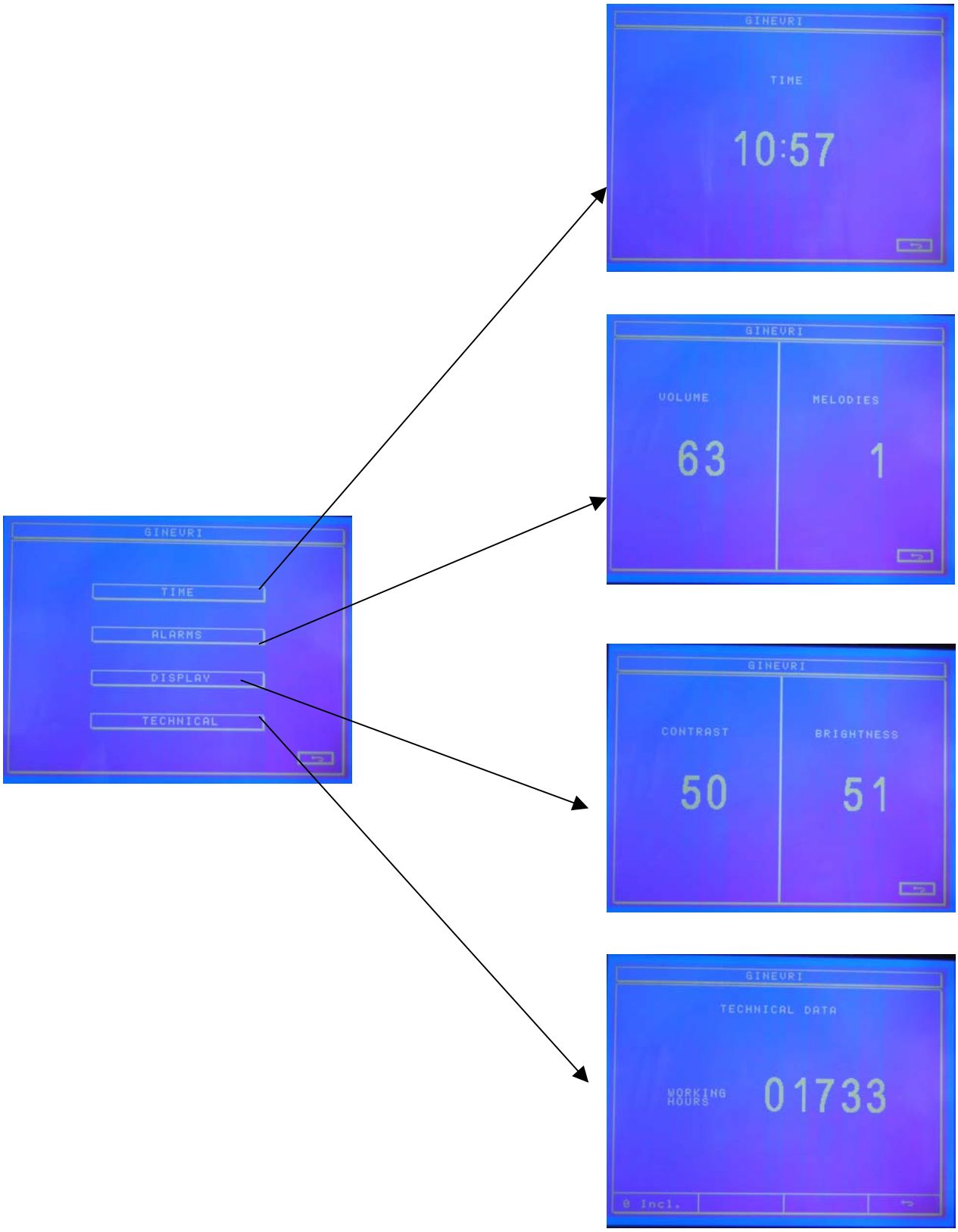


(SETTINGS DISPLAY)

- **ALARMS,** area reserved for the description of the active alarms will appear in the upper area in place of the word **Ginevri**
- **TIME,** active area to access the clock setting
- **ALARMS,** active area to access the settings for the alarm management by the user
- **DISPLAY,** active area to access the brightness of the display
- **TECHNICAL,** active area reserved for authorized technicians
- ↵**"return",** return to the Numeric Data Display




GINEVRI
TEMPERATURE TREND
HUMIDITY TREND
OXYGEN TREND
WEIGHT TREND
GINEVRI
AIR TREND
GINEVRI
HUMIDITY TREND
GINEVRI
OXYGEN TREND
GINEVRI
WEIGHT TREND


GINEVRI
TIME
ALARMS
DISPLAY
TECHNICAL
GINEVRI
TIME
10:57
GINEVRI
VOLUME
63
MELODIES
1
GINEVRI
CONTRAST
50
BRIGHTNESS
51
GINEVRI
TECHNICAL DATA
WORKING HOURS
01733
@ Incl.

## 5.3 THERMO-REGULATION IN AIR MODE (AIR MODE)

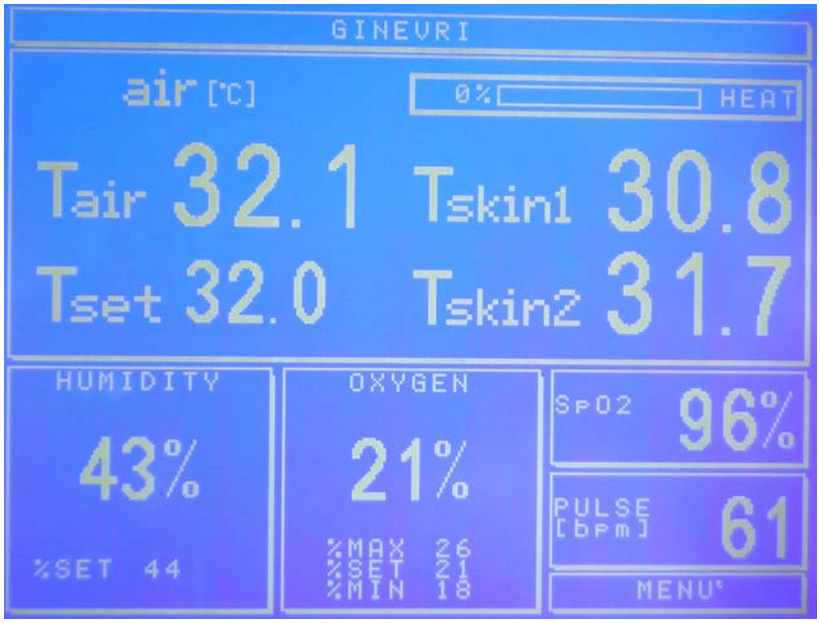



FIGURE (AIR MODE)

The OGB PolyTrend incubator allows for carrying out thermo-regulation in AIR Mode (AIR MODE) setting values between 20°C - 39 °C with 0.1 °C incremental steps.

To select the Air Mode function (AIR MODE) press on the “AIR SKIN” button (11) so that the corresponding LED on the Control Panel comes on, while on the display the writing [°C]” will appear in the position shown in the figure above (AIR MODE).
To set the temperature in the range 20°C - 37 °C, proceed as follows:

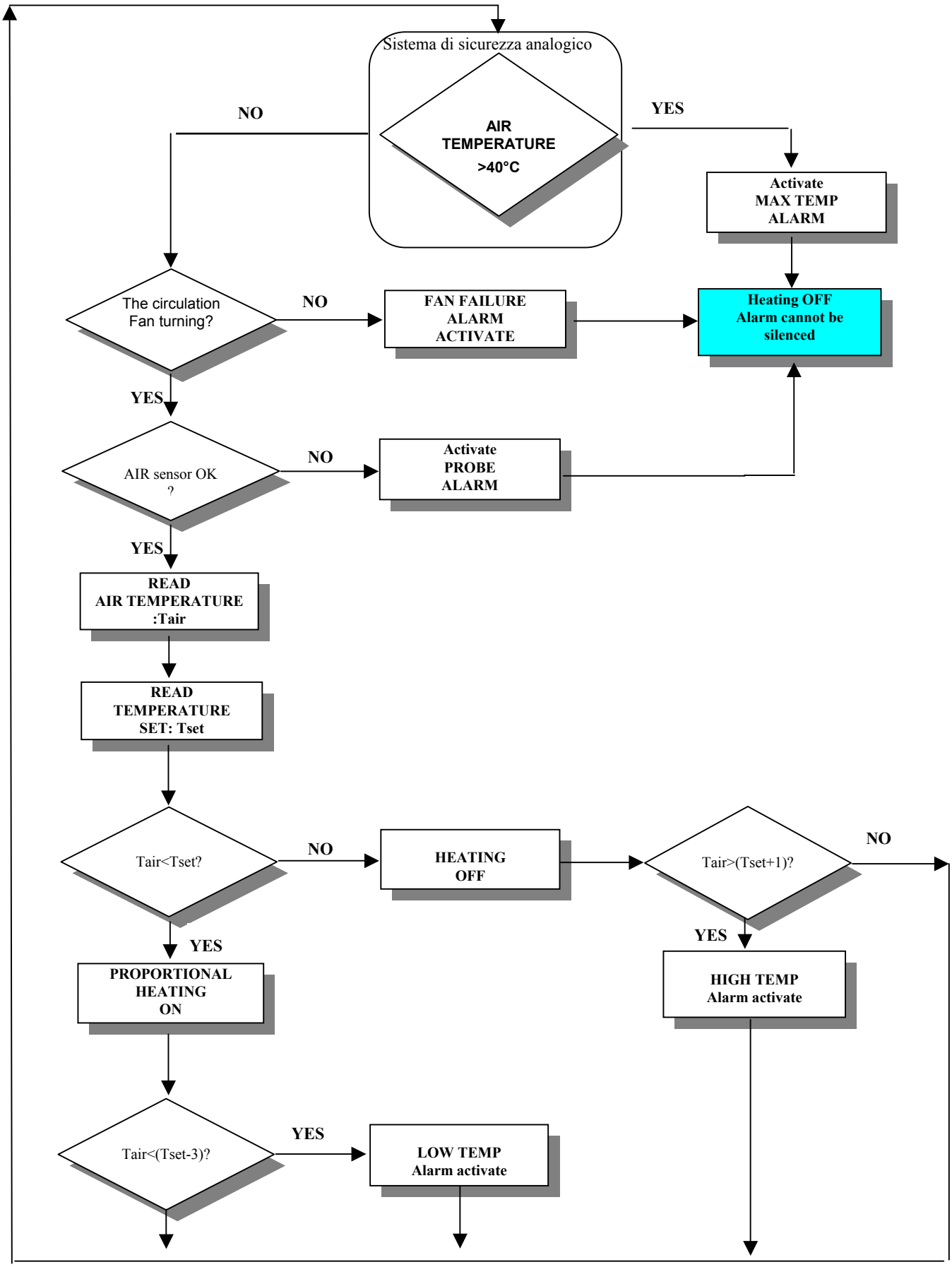
1. Press the Block button (8) if the encoder is blocked, with the corresponding LED switching off.
2. Turn the encoder to select the Tset value, the value of Tset, in fact, will appear.
3. Press the encoder to activate the setting.
4. Turn the encoder clockwise to increase the temperature setting and counter-clockwise to decrease the temperature setting.
5. Press the encoder to finish the operation, otherwise the operation will shut itself off after several seconds.

The temperature can be changed with incremental steps of 0.1 °C.
To set the >37°C, follow the same procedure with the difference that in the step between point 3 and point 4 the encoder must be kept pressed.

When the set temperature is >37°C on the display a flashing “>37” indicator (1)will appear.

The temperature value selected is memorized in the hard memory and is maintained even in case of loss of power. When the temperature selected is modified the Function Mode in use (AIR or SKIN) will also be memorized in the hard disk.

# WORKING DIAGRAM (FLOW-CHART) OF THERMO-REGULATION IN AIR MODE



TEMPERATURE TREND DISPLAY SCREEN

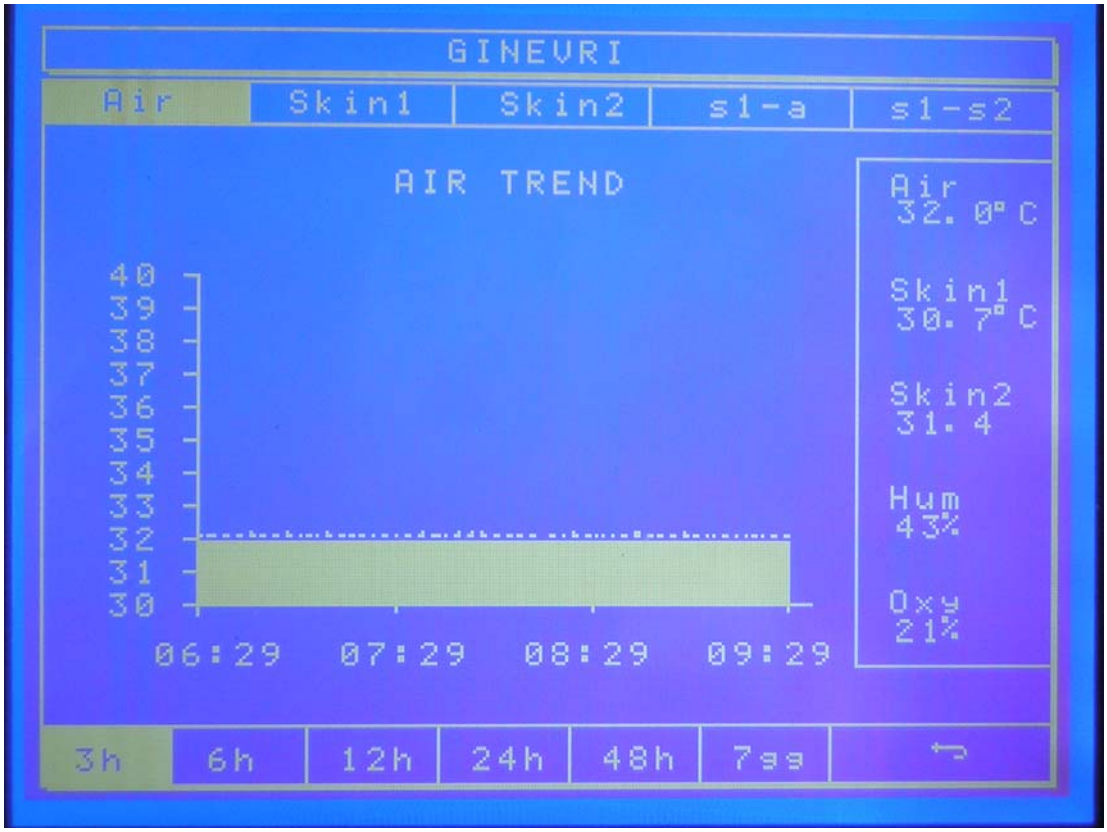



FIGURE (TEMPERATURE TREND DISPLAY SCREEN)

- **ALARMS**, area reserved for description of the activated alarms in the upper part of the screen replacing the GINEVRI name.
- **air**, internal air temperature of the hood.
- **skin1**, patient skin temperature (check).
- **skin2**, patient skin temperature (peripheral).
- **S1-a**, active area to visualise the Temperature Trends given by the difference between the SKIN and AIR sensor probes.
- **S1-S2**, active area to visualise the Temperature Trends given by the difference between the SKIN sensor probe and the PERIPHERAL sensor probe.
- **3h, 6h, 12h, 24, 48h, 7gg,** active are to visualise the relative Trends.

The "Temperature Trend" display is composed of graphs of the three monitored temperatures, on the base axis of each graph is shown the time, while on the vertical axis the reported temperature values are shown.
The first time on the left indicates the time the incubator was turned on.
Every graph has a vertical line showing the current time as well as on the graphs there is a horizontal line indicating the pre-set temperature.

## 5.4 THERMO-REGULATION IN SKIN MODE (SKIN MODE)

FIGURE (SKIN MODE)

The OGB PolyTrend incubator allows for carrying out thermo-regulation in SKIN Mode (SKIN MODE) setting values between 25°C - 39 °C with 0.1 °C incremental steps.

To select the SKIN Mode function (SKIN MODE) press on the "AIR SKIN" button (11) so that the corresponding LED on the Control Panel comes on, while on the display the writing "skin [°C]" will appear in the position shown in the figure above (SKIN MODE).

To set the temperature in the range 25°C - 37 °C, proceed as follows:

2. Press the Block button (8) if the encoder is blocked, with the corresponding LED switching off.
2. Turn the encoder to select the Tset value, the value of Tset, in fact, will appear.
6. Press the encoder to activate the setting.
7. Turn the encoder clockwise to increase the temperature setting and counter-clockwise to decrease the temperature setting.
8. Press the encoder to finish the operation, otherwise the operation will shut itself off after several seconds.

The temperature can be changed with incremental steps of 0.1 °C.

To set the >37°C, follow the same procedure with the difference that in the step between point 3 and point 4 the encoder must be kept pressed.

When the set temperature is >37°C on the display a flashing ">37" indicator (1)will appear.

The temperature value selected is memorized in the hard memory and is maintained even in case of loss of power.

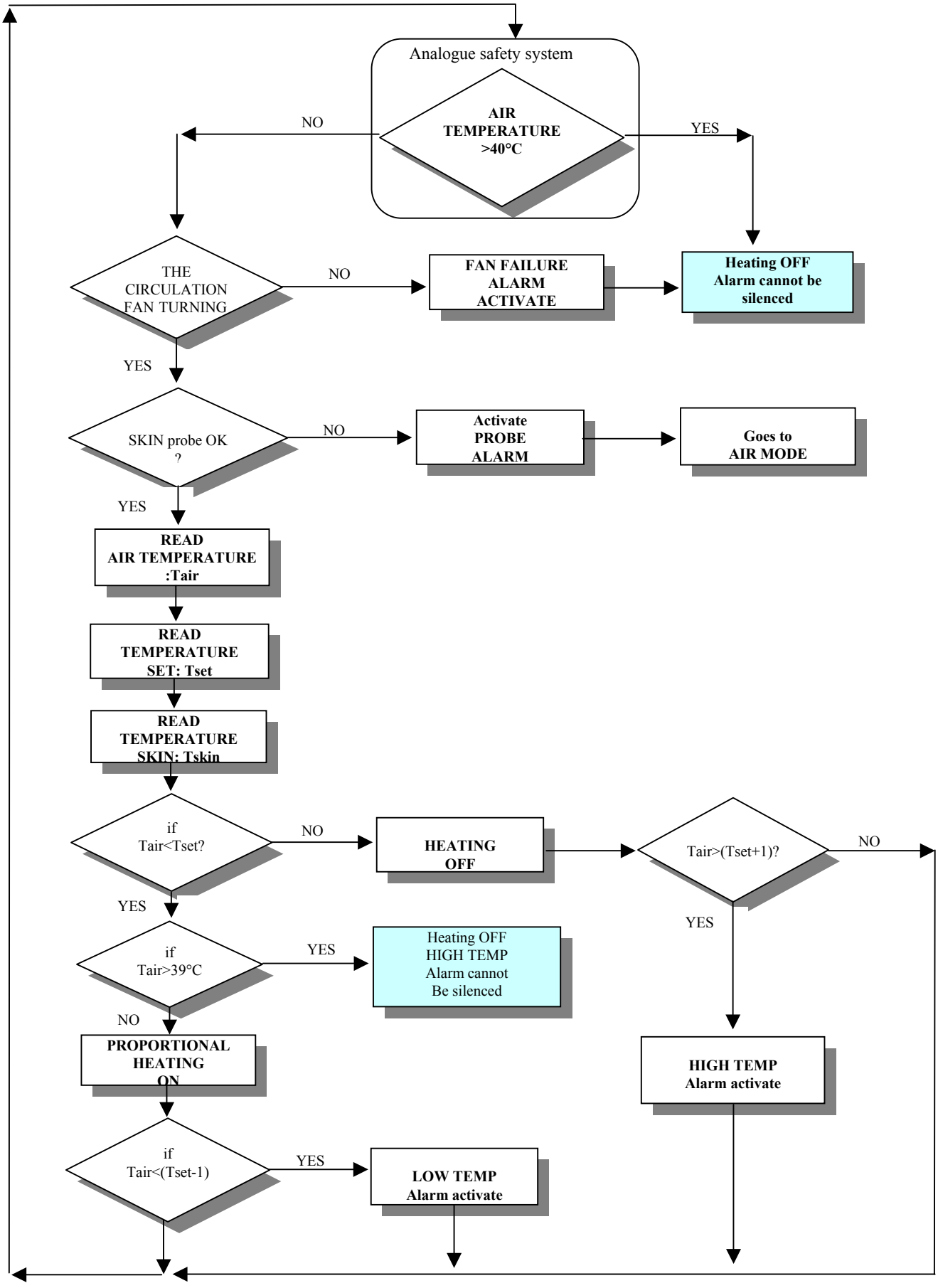
If during thermo-regulation in SKIN mode the SKIN1 sensor becomes disconnected, the “SKIN PROBE DISCONNECTED” alarm will activate, and the temperature will automatically be regulated in AIR mode to an initial setting of 33°. During thermo-regulation in AIR mode, however it is possible to disconnect the SKIN1 sensor probe with activating any alarms.

Position the thermo-metric sensor probe for reading the skin temperature in contact with the baby’s skin at the level of the abdomen, precisely between the belly button and the abdomen itself.

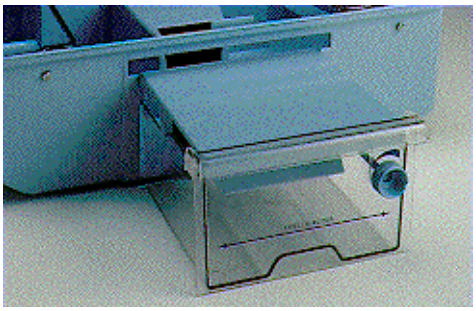
For a true and safe attachment we recommend the use of our probe fix gel (P/N 565).

The thermo-metric sensor probe for reading skin temperature must not be used as a rectal sensor except if it has been deliberately pre-prepared for that use.

# WORKING DIAGRAM (FLOW-CHART) OF THERMO-REGULATION IN SKIN MODE



## 5.5 STANDARD HUMIDIFICATION SYSTEM

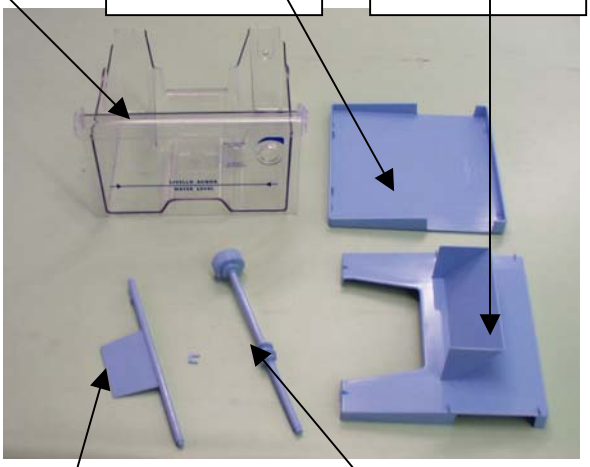


The standard humidification system, consisting of a basin, pressure fusion stamped out in polycarbonate, located in the rear part of the incubator base.
The basin’s transparency permits constant monitoring of the basin’s water level.
The variation of the humidity level (up to about 90%), is obtained through the use of a deflector, controlled by the specially designed lever which, depending on the position it is set in with respect to the hot air coming from the heating chamber, allows the desired humidity percentage to be reached in the hood interior..

The water basin can be taken out of the base with a simple pressure, simultaneously, on the two fixing levers located on the right and left sides of the basin itself.
This dismantling capability permits the basin to be cleaned and sterilized every time that it is felt to be necessary It is recommended to frequently carry this operation, even several times a day. **This takes into consideration the fact that it is not necessary to move the little patient from the incubator during this cleaning procedure.**

## MODE OF USE, MAINTENANCE AND OPERATION OF THE STANDARD HUMIDIFIER

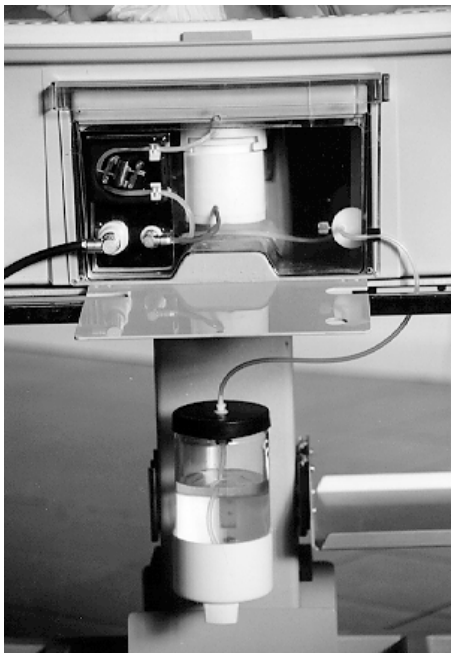
- **Extract the water container from the base pressing on the two spring levers on the sides;**
- **Lift the cover (blue);**
- **Clean and rinse out the transparent water container, the cover (made up of two half covers able to be dismantled and separated from each other) and il deflector with its related control group. These operations, can all be carried out without the need for any utensils;**
- **Fill the transparent water container with drinkable or distilled water up to the level marked by a line;**
- **Replace the cover(blue) into place;**
- **Insert the filled water container into the base with just enough pressure to make the two blocking levers "pop";**
- **Regulate the humidity to the desired level by using the specifically provided control handle.**




**In the hood, more or less condensation depends upon the difference between the ambient temperature and that of the incubator.**
**In normal conditions for confinement to bed, the humidity level is in the 50%- 65% range.**
**Whenever it is necessary to create a humidified, oxygenated environment with elevated temperature it is recommended to use a head box micro-climate.**
**The table shown below shows the relative humidity range with respect to the positioning of the regulating control handle : MINIMUM - MEDIIUM - MAXIMUM.**

| AMBIENT TEMPERATURE | ROOM HUMIDITY | INCUBATOR TEMP. | INCUBATOR HUMIDITY Minimum - Medium - Maximum | | |
|---|---|---|---|---|---|
| 24°C | 52% | 32°C | 60/65 | 65/75 | 75/90 |
| | | 35°C | 53/63 | 63/73 | 73/83 |

## 5.6 SERVO-REGULATION OF THE HUMIDITY LEVEL



**OGB PolyTrend** incubator is equipped with a ***"Servo-Steam"*** servo-controlled humidifier.
With the ***Servo-Steam*** it is possible to set and servo-control the humidity level inside the incubator hood up to a value of 90%.
The humidity generation system guarantees the production of sterile humidity inside the incubator because the evaporator, located in the standard humidifier housing, is isolated from the environment reserved for the patient and works at 135°C. The water reservoir is located on the exterior of the incubator and, therefore, only vapour enters and diffuses into the patient space.

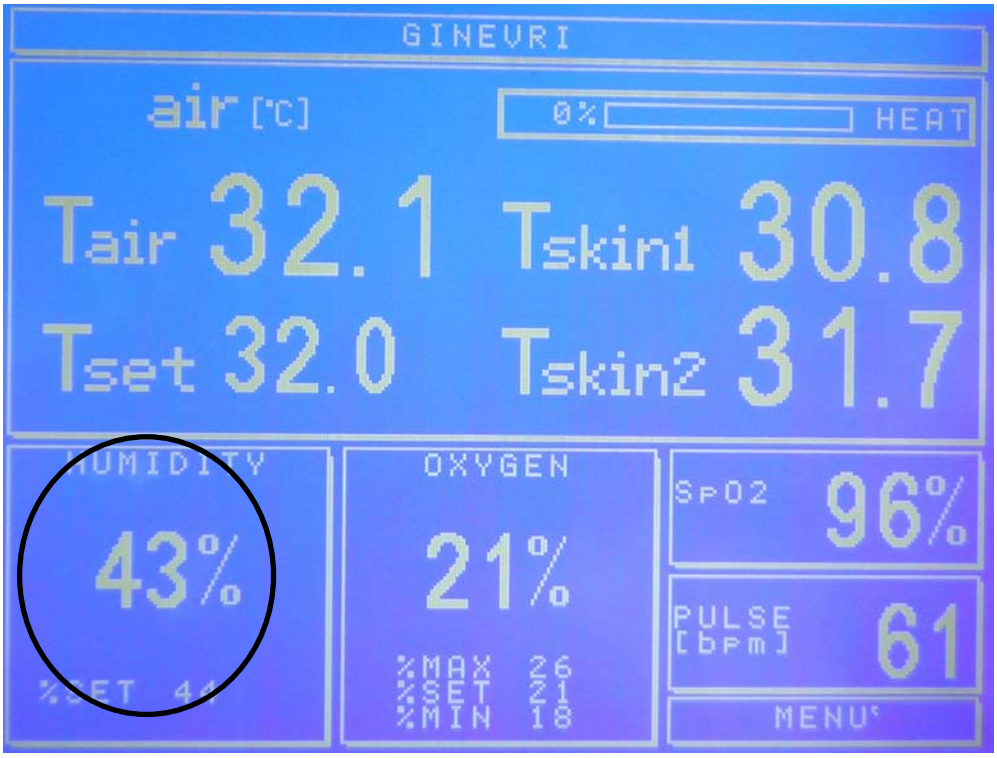



**FIGURE (Humidity visual display)**

**To set the humidity level between 15% - 90 %, proceed in the following way:**

1. **Press the Block button (8) if the encoder is blocked, the corresponding LED will then turnoff.**
2. **Rotate the encoder until the set % value in the humidity field is selected.**
3. **Press the encoder to activate the setting.**

4. **Rotate clockwise to increase the humidity value setting and anti-clockwise to decrease that value.**
5. **Press the encoder to terminate the operation, otherwise the operation will be automatically terminated after a few seconds.**

**Verify that the humidification holder of the *Servo-Steam* is correctly connected according to the instructions furnished in the incubator assembly section.**

**To avoid the formation of chalk deposits in the evaporation heating chamber we suggest the use of distilled water.**

**The relative humidity can be varied in 1% steps. The pre-set relative humidity value is memorized in the hard drive and is saved in case of power failure.**

**At high levels of relative humidity the formation of condensation on the inside walls of the incubator hood can occur. The condensation formation will be more consistent and substantial the greater the difference in temperature between the temperature inside the of the incubator and the outside ambient temperature.**

HUMIDITY TREND DISPLAY SCREEN

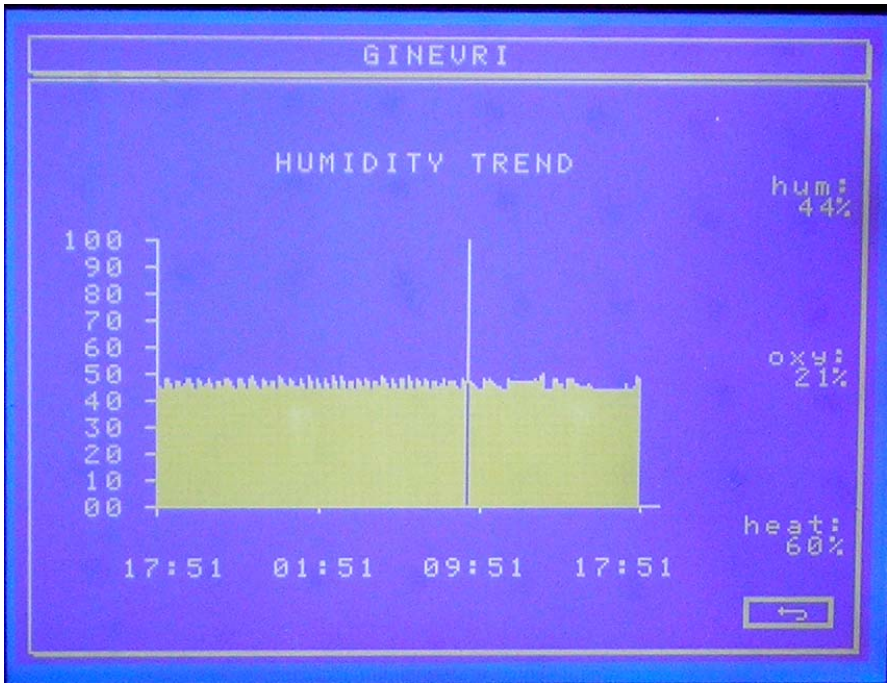



FIGURE (HUMIDITY TREND DISPLAY SCREEN)

- **ALARMS**, area reserved for description of the activated alarms in the upper part of the display replacing the GINEVRI name.
- **air**, internal air temperature of the hood.
- **skin1**, patient skin temperature (check).
- **skin2**, patient skin temperature (peripheral).
- **S1-a,** active area to visualise the Temperature Trends taken from the difference between the SKIN and AIR sensor probes readings.
- **S1-S2**, active area to visualise the Temperature Trends taken from the difference between the SKIN sensor probe and the PERIPHERAL sensor probe readings.
- **3h, 6h, 12h, 24, 48h, 7gg**, active area to visualise the relative Trends.

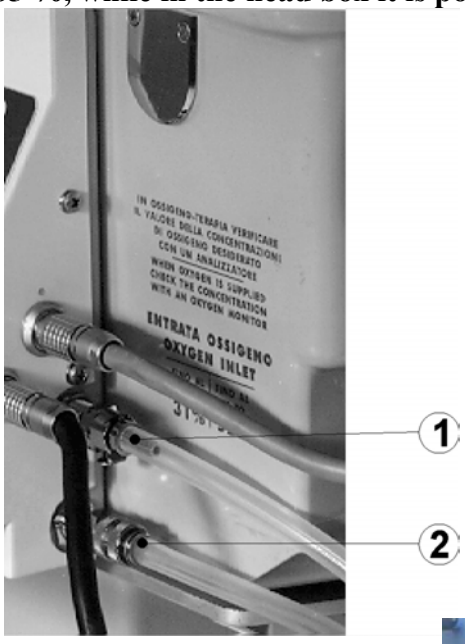
The "humidity trend" graphs the incubator's internal humidity level, on the base axis of each graph is shown the time, while on the vertical axis the reported humidity values are shown.
The first time on the left indicates the time the incubator was turned on.
Every graph has a vertical line showing the current time.

## 5.7 OXYGEN SERVO-CONTROL AND MONITORING SYSTEM

The **OGB PolyTrend** can be equipped, upon request, with an oxygen servo-control and monitoring system which allows the **setting of values between 21% to 65% in the hood, while in the micro-climate head box from 21% to 99% ,this without alterations to the micro-climate and with low flow supply.**.

**The incubator is also equipped with an automatic recognition system of the oxygen supply, in either the hood or the micro-climate head box.**

**For safety reasons, the maximum oxygen concentration attainable inside the hood has been limited to 65 %, while in the head box it is possible to set values up to 99 %.**




**To use the servo-control** you need to connect the incubator to the hospital oxygen supply system or to an oxygen tank. The incubator can be connected directly **to the supply source and does not require reducers or external pressure regulators.**

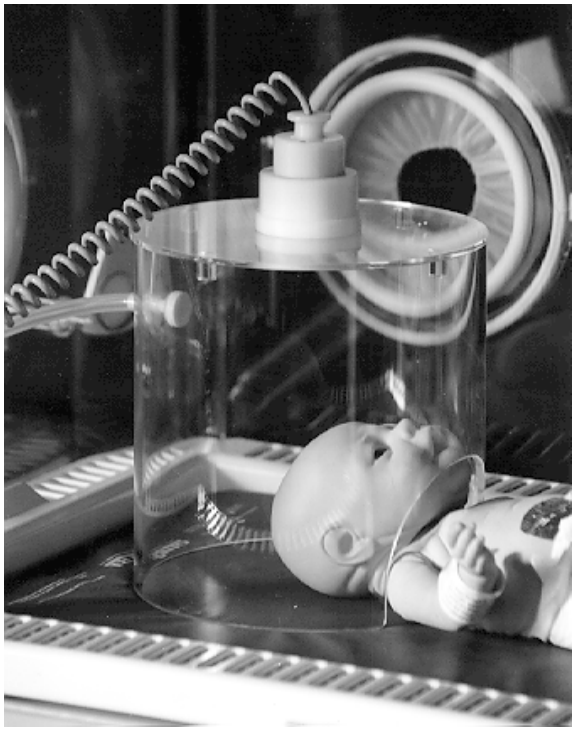
The connecting tube, suitable for the supply pressure, must be connected to the inlet **(1)** located on the right side of the control panel and labelled with: ***OXYGEN INLET***.

The micro-climate head box supply tube, at low pressure, must be connected to the inlet (2) located on the right side of the control panel and labelled with: ***OXYGEN TO THE HEAD BOX.***

**The oxygen sensor probe connector is connected in the specially provided inlet OXY PROBE located on the left side of the control panel.**

To carry out calibration you need to insert the sensor in the holder provided (see the section regarding the calibration operation page 34).

Position the sensor inside the hood or inside the micro-climate head box, the incubator will automatically select the oxygen supply operating mode: either hood or micro-climate head box.



WARNING:
To obtain an optimal calibration of the oxygen concentration sensor, you need to act as follows:

- Introduce the sensor into the specially provided holder located inside the incubator hood or inside the micro-climate head box;
- Keep it in that holder for all the incubator’s re-heating phases and, in any case for about 30 minutes, with the incubator itself already working (that is to avoid calibration errors and therefore measurements because of differences between the ambient temperature 21°C- 26°C and the working temperature 31°C- 36°C);
- Take the sensor from the interior of the hood or micro-climate head box and insert it in to the provided sensor holder located outside the hood, precisely on the back left side of the trolley, in the area protected by the handles – (see page 11) where an oxygen concentration of 21% is certain.
- activate the calibration process which does not take.
- Re- introduce the sensor probe into the sensor holder inside the hood or micro-climate head box..

The OGB PolyTrend incubator can be quipped with an oxygen concentration servo-control and monitoring system with allows for the setting of levels between 21% to 65% in the hood, while in micro-climate head box from 21% to 99% , this without alterations to the micro-climate and with low flow oxygen supply.

**The incubator is also equipped with an automatic recognition system of the oxygen supply, in either the hood or the micro-climate head box.**
**For safety reasons, the maximum oxygen concentration attainable inside the hood has been limited to 65 %, while in the head box it is possible to set values up to 99 %.**

The Incubator upon switching on or Resetting , if the oxygen sensor probe is not inserted in the calibration holder, the $O_2$ concentration reading system will indicate the necessity for the sensor probe to be calibrated, showing on the LCD display, in the oxygen reading part of the screen, the symbol "**- -** ". In this case all the alarms relating to oxygen are disabled.

In the case of, on switching on or Re-setting of the incubator, the probe is found to be inserted in the calibration holder, the calibration procedure will automatically commence signalling to the operator on the LCD display, in the oxygen reading part of the screen, the writing "**CAL"**. At the end of the calibration the "**CAL"** writing will be substituted by the air oxygen concentration level, ie. "**21%**".
Always remember, that if on switching on or Re-setting the incubator, the oxygen sensor probe connector is not connected the servo-control and monitoring and all the alarms connected to the oxygen sensor probe are completely disabled. If instead the disconnection, of the oxygen sensor probe, occurs during normal use the "**OXY PROBE DISCONNECTED**" will activate, thereby advising the operator of the disconnection. In this last case by pressing on the "MUTE" button you will have the possibility to disable the oxygen servo-control, monitoring and all the alarms relating to oxygen. If at the end of the calibration the writing "**OXY PROBE DISCHARGED**" appears it means that the oxygen sensor probe is depleted. It will not be possible to carry out a new calibration until this is substituted with a new sensor probe.

The "Oxygen Trend" diagram including the oxygen graphic, on the axis of that graphic is shown the selected temperature, while on the frame the oxygen level is shown.
On the right of the screen there is a frame which shows the fundamental parameters monitored in real time.

OXYGEN TREND DISPLAY SCREEN

FIGURE (OXYGEN TREND DISPLAY SCREEN)

- **ALARMS**, area reserved for description of the activated alarms in the upper part of the display replacing the GINEVRI name.
- **air**, internal air temperature of the hood.
- **skin1**, patient skin temperature (check).
- **skin2**, patient skin temperature (peripheral).
- **S1-a,** active area to visualise the Temperature Trends taken from the difference between the SKIN and AIR sensor probes readings.
- **S1-S2**, active area to visualise the Temperature Trends taken from the difference between the SKIN sensor probe and the PERIPHERAL sensor probe readings.
- **3h, 6h, 12h, 24, 48h, 7gg**, active area to visualise the relative Trends.

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The "Oxygen Trend" display graphs the oxygen trend taken from the dedicated sensor probe. On the base axis of each graph is shown the time, while on the vertical axis the reported oxygen level values are shown.
The first time on the left indicates the time the incubator was turned on.
Every graph has a vertical line showing the current time.

**To carry out the calibration** position the sensor probe in the provided calibration holder, proceeding as indicated in the figure and taking care that the knob sticking out of the body of the sensor holder goes into its matching groove. The insertion in the sensor holder, automatically activates the calibration procedure which lasts roughly 2 minutes, shown by the "**CAL**" indicator on the LCD display.

The incubator, at the end of the calibration procedure, will set itself in Monitoring Mode and the screen will **show the current oxygen concentration level reading** in the display screen frame dedicated to that reading.

Attention! Always carry out the sensor calibration in an environment with an air oxygen concentration level equal to 21 %. If you do not follow this procedure then false readings or probe malfunction alerts can occur.
After calibration and before use, it is always very useful to verify the calibration itself with a known oxygen concentration.
The most easily available calibration gases are: air (21%) and pure oxygen (100)%.
Finally, to obtain a more stable reading of the FiO2 it is important that the sensor probe is at the same temperature as the patient environment: therefore, leave it inside the hood during the incubator pre-heating phase.

To use the oxygen servo-control connect the incubator to the oxygen supply system following the instructions supplied in the Incubator Assembly section.

If the oxygen therapy is to be carried out directly inside the hood, position the sensor probe inside the hood itself. If, instead, the head box micro-climate is used, then position the sensor probe in the provided holder located in the head box itself, taking care that the hub on the sensor enters into the matching holder groove: this operation activates the oxygen supply in the head box.

The sensor is always put vertically into place with the egress at the bottom, in order to avoid the possible formation of condensation water drops which can fall onto the baffle and alter the readings.

To enable the servo-control mode from the "Numeric Data Display Screen":
set the O2 percentage in the range between 21% - 99% proceed as follows:

1. **Press the Block button (8) if the encoder is blocked, with the corresponding LED then turning off.**
2. **Rotate the encoder until the set % value in the oxygen field is selected.**
3. **Press the encoder to activate the setting.**
4. **Rotate in a clockwise direction to increase the oxygen value setting and anti-clockwise to decrease that value.**
5. **Press the encoder to terminate the operation otherwise the operation will be automatically terminated after a few seconds.**

The oxygen concentration can be varied in step increments of 1%.

To limit the flow and for other safety reasons the maximum oxygen concentration obtainable inside the hood is limited to 65%; while in the head box micro-climate you can select and achieve values up to 99%.

The selected oxygen concentration value is memorized in the hard disk and will be saved even in the case of power failure.

## OXYGEN INLETS

The **OGB PolyTrend** is also equipped with two inlets for the administration of pure oxygen:

- One, limits the oxygen concentration inside the hood, to 31%;
- The other , limits the oxygen concentration inside the hood to 52 %.

Both inlets are positioned on the front part of the filter holder.

## WARNING

When oxygen is administered, it is important to use an oxygen concentration analyser or a pulse oxymeter.

OXYGEN CONCENTRATION INLET TABLE (31%)

**Measurements taken with a flux metre connected to the 31% inlet:**

| Rate of Flow | Oxygen Concentration |
|---|---|
| l.p.m. 1 | 22.7 % |
| l.p.m. 2 | 23.7 % |
| l.p.m. 3 | 25.1 % |
| l.p.m. 5 | 29 % |
| l.p.m. 6 | 29.7 % |
| l.p.m. 7 | 30.3 % |
| l.p.m. 8 | 31 % |
| l.p.m. 9 | 31.5 % |
| l.p.m. 10 | 31.5 % |

OXYGEN CONCENTRATION INLET TABLE (52%)

**Measurements taken with a flux metre connected to the 52% inlet:**

| Rate of Flow | Oxygen Concentration |
|---|---|
| l.p.m 5 | 31 % |
| l.p.m. 10 | 43.5 % |
| l.p.m. 15 | 43.5 % |
| l.p.m. 18 | 46 % |
| l.p.m. 20 | 51.5 % |
| l.p.m. 25 | 52 % |
| l.p.m. 30 | 52 % |

## 5.8 CLOCK

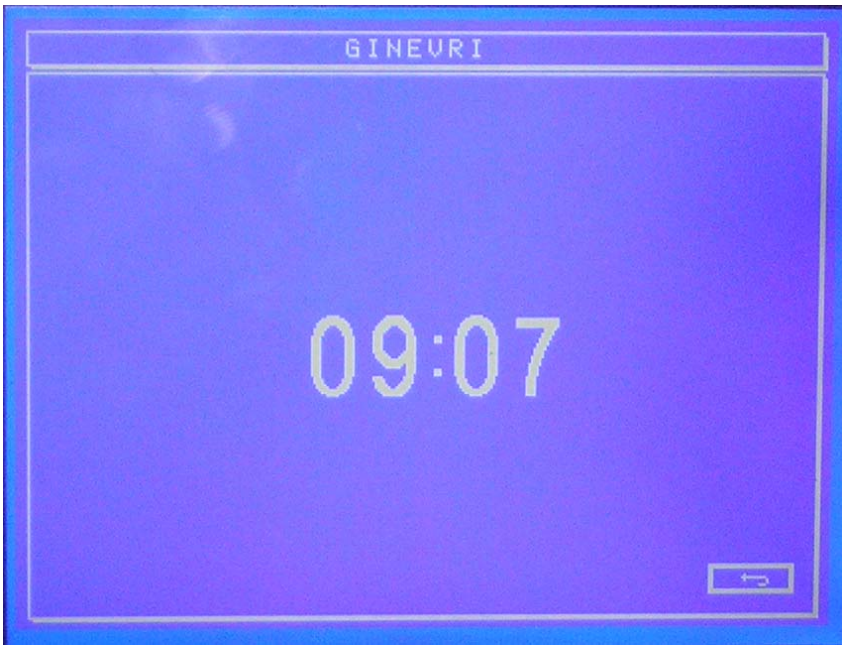



FIGURE (TIME SET DISPLAY SCREEN)

- **ALARMS**, area reserved for description of the activated alarms in the upper part of the display replacing the GINEVRI name.
- **SETTING HOURS,** shows the hours of the clock, it is possible from this field to modify the internal clock time, in this case data from memorized trends will be cancelled.
- **SETTING MINUTES**, shows the minutes of the clock, it is possible from this field to modify the internal clock time and in this case data from memorized trends will be cancelled.
- ↵ “return”, return to the Numerical Data Display Screen.

## 5.9 TIME SETTING

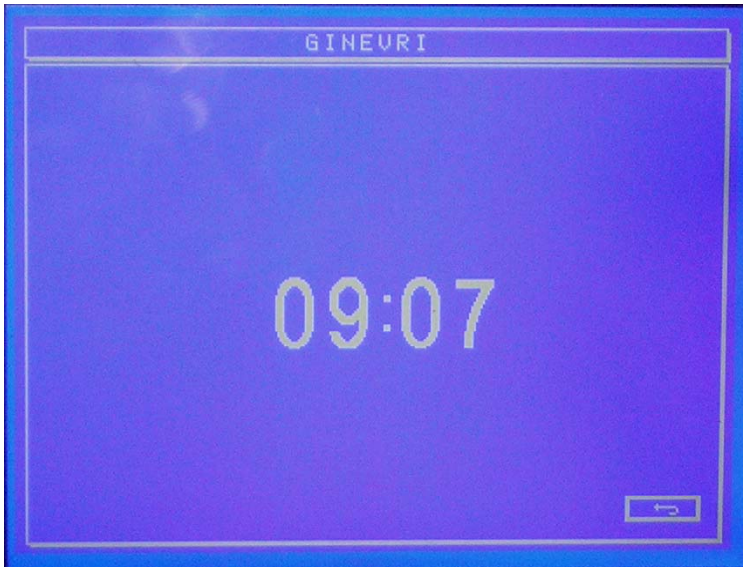



**FIGURE (viewing the time with the selected field)**

The incubator is equipped with an internal clock for management of the trends. It is possible to set the hour and the minutes of the internal clock from the "TIME" screen. To access that screen from the Numerical Data Screen select the Menu field and press the encoder. From the Menu screen select the Settings field and press the encoder, from the Settings screen select the Time field and press the encoder.

From the "Time" screen :

1. **Press the Block button (8) if the encoder is blocked, with the corresponding LED then turning off.**
2. **Rotate the encoder until the desired hours or minutes are selected.**
3. **Press the encoder to activate the setting.**
4. **Rotate clockwise direction to increase the hour or the minute to set and anti-clockwise to decrease those values.**
5. **Press the encoder to terminate the operation otherwise the operation will be automatically terminated after a few seconds.**

Setting the Time brings also results in the cancellation of all the memorized trend data because the samples were taken at times corresponding to a different reference system, consequently the trend graphs will return to the original axis.

## 5.10 SETTINGS DISPLAY

**FIGURE (SETTINGS DISPLAY)**

- **ALARMS**, area reserved for the description of the alarms which are active will appear in the upper area in place of the writing GINEVRI.
- **CONTRAST**, indicates the contrast setting for the display. The contrast is modifiable by selecting the active area and turning the encoder to increase or decrease the intensity.
- **BRIGHTNESS** indicates the brightness setting for the display. The brightness is modifiable by selecting the active area and turning the encoder to increase or decrease the brightness.
- ↵ **“return”**, return to the numerical data screen..

## 5.11 TECHNICAL SETTINGS

**FIGURE (TECHNICAL SETTINGS DISPLAY SCREEN )**

- **ALARMS,** area reserved for the description of the alarms which are active will appear in the upper area in place of the writing GINEVRI.
- **WORKING HOURS Visualization** of the number of machine's working hours.
- **0 INCL** Active area for zero-ing of the incline meter of the scales (see scales manual).
- ↵ **"return",** return to the initial numeric data display screen.

## 5.12 SETTING THE VOLUME AND TYPE OF ALARM MELODY

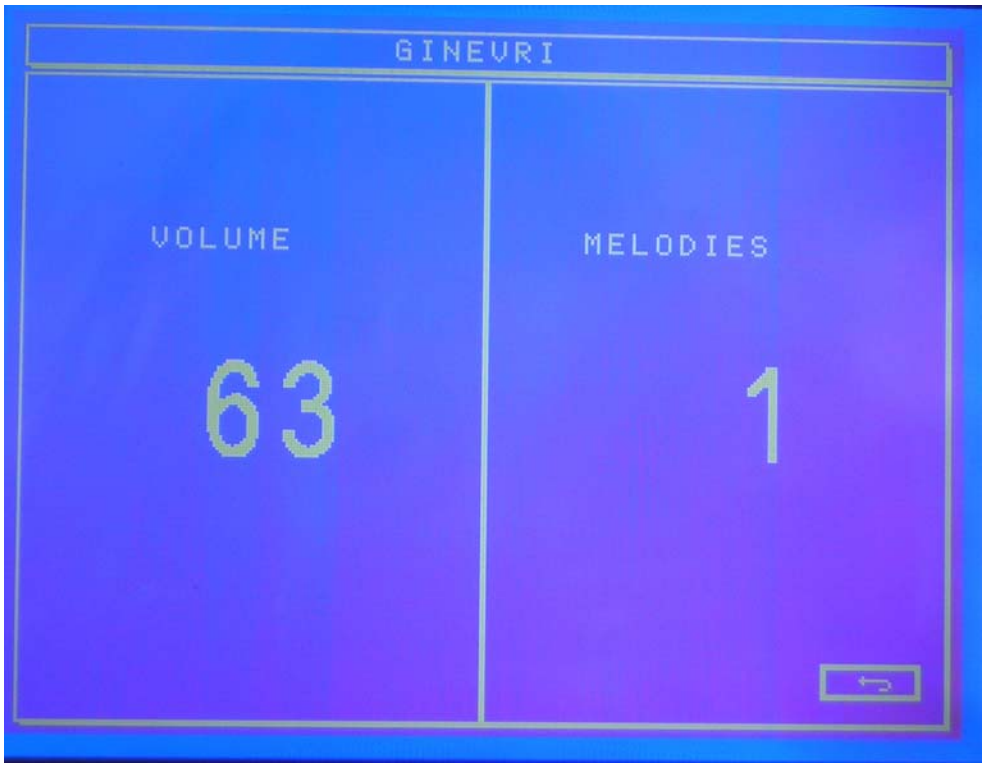



**FIGURE (ALARM SETTINGS DISPLAY SCREEN)**

- **ALARMS,** area reserved for the description of the alarms which are active will appear in the upper area in place of the writing GINEVRI.
- **VOLUME SETTING**, indicates the volume setting for the alarms.
- **SELECTED MELODY,** indicates the melody selected
- ↵ “return”, ritorno alla schermata dati numerici.

## 5.13 ALARMS

All the settings and readings taken from the sensors are shown on the graphic monochrome display in the centre of the Control Panel. Different settings and visualizations are accessible by using the different displays available on the monitor.

The high part of the liquid crystal display is dedicated to visually displaying descriptions of the alarms:

- **HIGH TEMPERATURE**, is seen when the air temperature inside the hood exceeds the set temperature by 1°C or when the skin temperature exceeds the set temperature by 1°C.
  Otherwise, there is an alarm controlled by the micro-processor which is activated when the air temperature inside the incubator exceeds 39.5°C. This last type of alarm cannot be Muted.
- **LOW TEMPERATURE**, when the air temperature in hood is inferior of 3°C respecting to setting temperature, or when the setting temperature is inferior of 1 °C respecting to sertting temperature.
- **MAX TEMP**, is controlled by a protective analogue circuit independent from the micro-processor and is activated at 40°C.
- **HIGH HUMIDITY**, (when requested) indicates the state of the alarm for high percentages of humidity, and is activated when the level of humidity reading is 10% higher than the pre-selected value.
- **LOW HUMIDITY**, (when requested) indicates the state of the alarm for high percentages of humidity, and is activated when the level of humidity reading is 10% lower than the pre-selected value.
- **HIGH OXYGEN**, (when requested) indicates the state of the alarm for high oxygen concentration, and is activated when the oxygen concentration reading is higher than the pre-selected maximum value.
- **LOW OXYGEN**, (when requested) indicates the state of the alarm for high oxygen concentration, and is activated when the oxygen concentration reading is lower than the pre-selected minimum value.
- **FAN FAILURE**, Blocked fan alarm is activated if the air circulation fan is blocked or slows down. In this case both the visual and auditory alarms are activated, (not mutable) and heating is suspended.
- **AIR PROBE FAILURE**, this alarm is activated for a broken air probe when the temperature difference between the air sensor probe and the test sensor located at the same place is greater than 1°C.
- **SKIN PROBE DISCONNECTED**, this alarm is activated when the Skin1 sensor probe becomes disconnected and the incubator is in Skin thermo-regulation Mode, in this case the thermo-regulation passes to Air Mode with the temperature set at 33°C.
- **PROBE CABLE DISCONNECTED**, disconnected probe cable alarm is activated when the probe group wire is disconnected. When this occurs heating and all of the machine's other functions are suspended.
- **OXY PROBE DISCONNECTED**, (when requested) the Disconnected Oxygen Sensor Probe Alarm is activated when the oxygen sensor probe is disconnected. The alarm can be silenced by pressing the Mute button.
- **WRONG OXY PROBE POSITION,** (when requested) Alarm for the incorrect positioning of the oxygen sensor probe. If it is activated, not having done the calibration, the sensor probe is positioned in the probe door in the hood or in the small

cap. Otherwise it is activated, after having done the calibration, if the oxygen probe is not in one the two reading positions; to move the probe to a new position, the user has approximately one minute before the alarm is activated.

- **DISCHARGED OXY PROBE,** (when requested) **Discharged Sensor Probe Alarm** is activated when the oxygen sensor probe is discharged. The alarm is both visible and acoustic and can only be silenced by pressing thee Mute button. The alarm is deactivated if the sensor probe is disconnected. A new calibration cannot be done until the sensor probe has been substituted with a new one.
- **PRE-HEATING,** Indication that the incubator is still in its warm-up phase: for the mutable alarms the acoustic alarms are inhibited. The maximum duration of this alarm is 25 minutes, and it is cancelled if the temperature reading is 0.9°C lower than the set temperature. This indicator is activated only if on turning the incubator on the air temperature is lower than 28°C.

- High SpO2, MAX SpO2 alarm, indicates an oxygen percentage in the blood above the selected limit.

- Low SpO2, MIN SpO2 alarm, indicates an oxygen percentage in the blood below the selected limit.

- High Pulse Rate, MAX Pulse Rate alarm, indicates a cardiac frequency above the selected limit.

- Low Pulse Rate, MIN Pulse Rate alarm, indicates a cardiac frequency below the selected limit.

- SPO2 sensor, incorrect positioning of the sensor probe and the lack of connection, will be indicated in the area reserved for alarms.

**The red LED "Alarm" warning comes on at the same time as the acoustic warnings of the above mentioned alarms. In the case of more than one alarm being activated simultaneously the number of alarms will be shown as well as the type of alarms' description will be alternately shown.**

### 5.13.1 Hi and low air temperature alarms (air)

The HI and LOW AIR TEMPERATURE Alarms are automatically set when the desired AIR TEMPERATURE level to be reached is selected. They come into function when the temperature goes above by 1°C (HIGH TEMP) or goes below by 3°C(LOW TEMP).

The alarms can be muted by pressing on the "**MUTE**"(3) key; in this state the red LED corresponding to the alarm (4) will flash until the temperature level goes back to the normal level. If the alarm condition lasts for more than 10 minutes the alarm sounding will be automatically reset.

A "MAX TEMP" alarm is present, controlled by an protection analogue circuit independent from the micro-processor which is activated when the air temperature inside the incubator hood reaches 40°C or the heating element reaches too high of a level.
The "MAX TEMP" alarm is controlled by an protection analogue circuit independent from the micro-processor which is activated when the air temperature inside the incubator hood reaches 40°C. In this condition the heating will be suspended and the alarm will sound and cannot be silenced. The incubator will be switched off and the high air temperature diminishes.

**In any case if the air temperature goes above 39°C the HIGH TEMP alarm will activate in a non-mutable way until the air temperature is re-set to a level less than 39°C, in this case the incubator heating will be stopped**.

These alarms are also sensitive to outside heat sources such as: phototherapy lamps, sunlight, radiators, etc.

### 5.13.2 Hi and low skin temperature alarms (skin)

The HI and LOW SKIN TEMPERATURE Alarms are automatically set when the desired SKIN TEMPERATURE level to be reached is selected. They come into function when the temperature goes above (HIGH TEMP) or goes below (LOW TEMP) the selected value by 1°C.

The alarms can be muted by pressing on the "**MUTE**"(3) key; in this state the red LED corresponding to the alarm (4) will flash until the temperature level goes back to the normal level. If the alarm condition lasts for more than 10 minutes the alarm sounding will be automatically reset.

In SKIN Mode, if the patient sensor probe is correctly positioned, the thermo-regulation system will automatically limit the air temperature to 39°C.
In this mode an accurate and rapid heating of the patient is obtained without the air temperature inside the hood going above the allowed limits before the patient reaches the selected skin temperature.

In any case if the air temperature goes above 39°C the HIGH TEMP alarm will activate in a non-mutable way until the air temperature is re-set to a level less than 39°C, in this case the incubator heating will be stopped.

### 5.13.3 Hi and low relative humidity alarms

The HI and LOW RELATIVE HUMIDITY Alarms are automatically set when the humidity level is selected and come into function when the humidity, inside the hood, goes above or falls below the selected level by 10%.

The alarms can be muted by pressing on the "**MUTE**"(3) key; in this state the red LED corresponding to the alarm (4) will flash until the humidity level goes back to the normal level. If the alarm condition lasts for more than 10 minutes the alarm sounding will be automatically reset.

### 5.13.4 Hi and low oxygen concentration alarms

The HI and LOW Oxygen Concentration Alarms can be set either automatically or manually.

For Automatic setting you simply need to input the concentration level you want to reach ("%set"), the alarms come into function when the oxygen concentration reading is different by ±10% from the selected level.

**To Manual Setting proceed as follows:**

1. **Press the Block button (8) if the encoder is blocked, with the corresponding LED then turning off.**
2. **Rotate the encoder until the MAX % or MIN % level in the oxygen field is selected.**
3. **Press the encoder to activate the setting.**
4. **Rotate clockwise direction to increase the MAX limit or the MIN limit and anti-clockwise to decrease those values.**
5. **Press the encoder to terminate the operation otherwise the operation will be automatically terminated after a few seconds.**

The alarms come into operation when the oxygen concentration reading goes above the selected MAX level or less than the selected MIN level.

The alarms can be muted by pressing on the "**MUTE**"(3) key; in this state the red LED corresponding to the alarm (4) will flash until the oxygen concentration level goes back within the desired limits. If the alarm condition lasts for more than 10 minutes the alarm sounding will be automatically reset.

## 5.14 Bed height adjustment (only in height adjustable version)

To the incubator's height, you only need to press on the activator pedal on the base of the OGB POLYTREND.
Especially there are two pedals, the pedal with the up arrow raises the incubator, the pedal with the down arrow brings down the incubator.

# 6. INCUBATOR ASSEMBLY

All the OGB PolyTrend incubators have been designed to simplify and make more efficient maintenance, cleaning, and sterilization procedures.

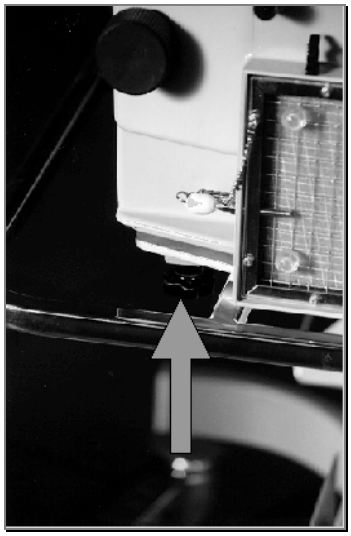
All the incubators components are easily taken apart in just a few minutes and without needing any tools.

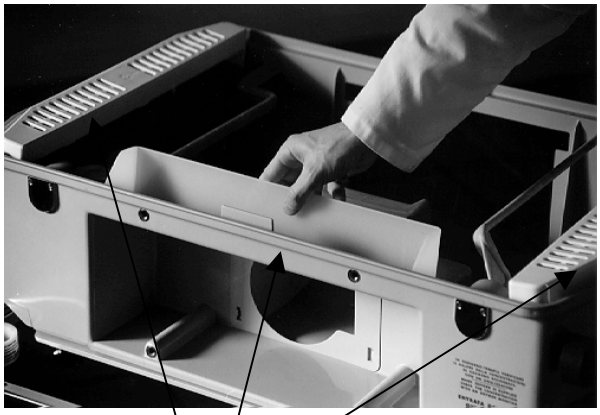
All the electrical power components are contained in the control panel and are easily removable.

## 6.1 BASE

**A system of attachment points has been designed to securely fix the incubator to the trolley.**

Place the incubator on the specially design trolley top, in such way that the " feet" of the base itself go into the specially provided footings in the trolley top and connect the 4 screw bolts to hold everything together (trolley and incubator).



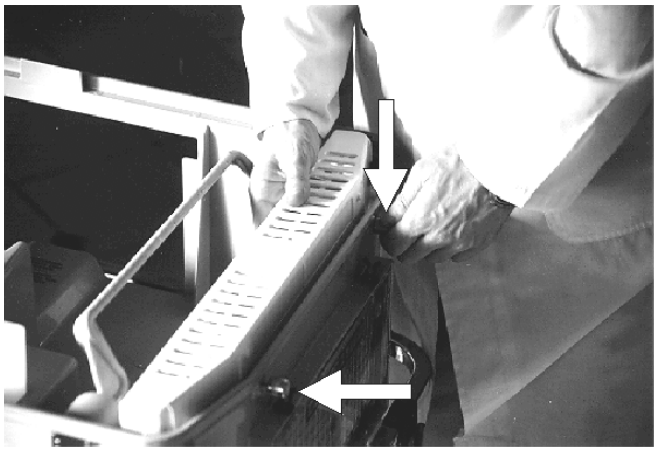


Insert into the fixing points specially provided in the base.

**AIR CONVEYOR**

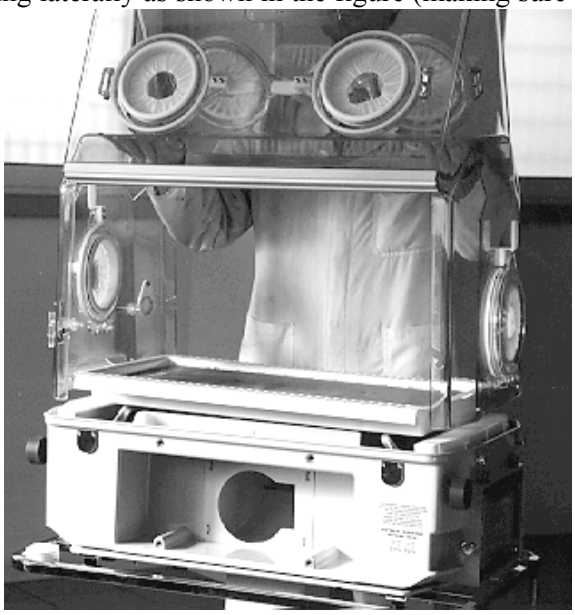
**Side bars, with vent slits, close the hood**

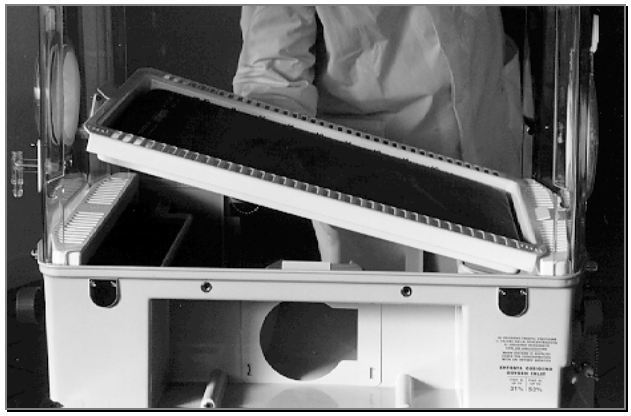
Connect them, internally to the base, closing them with the rounded chrome bolts provided. Do not screw the above mentioned knobs in until the footings of the incubator hood have been put into place. After that, tighten them down making sure that the two knobs sticking out from the sidebars enter to the corresponding holes in the hood.



## 6.2 HOOD

To mount the hood onto the base, lift it with the palms of the hands as shown in the figure and put into place on the base so that the sidebar/base gaps match up and correspond.
To put the patient bed tray into the incubator do as follows. Lower the ***Smooth-Tilt*** arms completely rotating the provided blue handles located on the sides of the base (left and right). Insert the patient tray inclining laterally as shown in the figure (making sure it is put in towards the end with FRONT written on it). To take it out simply do the opposite.



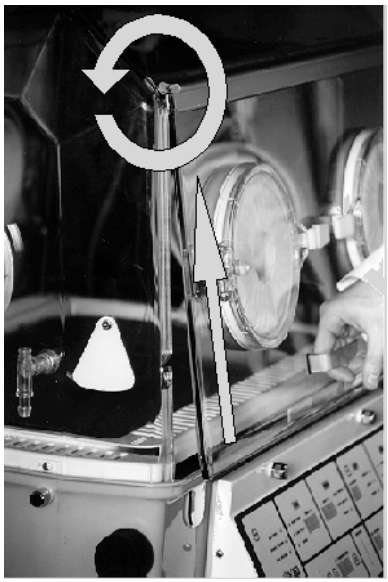


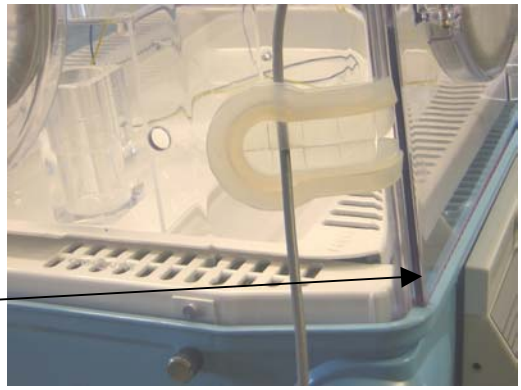
To disassemble the doors loose both the screws and slide the hinge out.

Both the doors should be kept close during routine operation. For infant safety, do not leave the infant unattended while the doors are open.

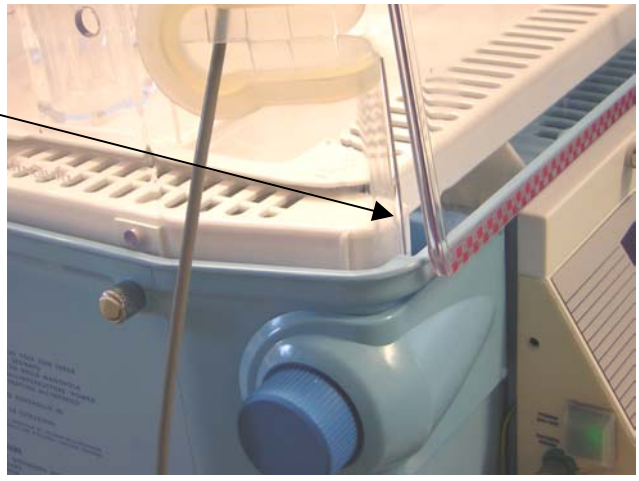
**WARNING**

Closing the doors, check that the bottom side of the door is inserted in the base slot as shown in the figure.





N.B. When the door panel is properly closed its lower red edge is not visible.



## 6.3 MICRO-FILTER

A NON-PERVIOUS Micro-filter leads to:

- Incubator internal air contamination;
- Limitation of the quantity of air in circulation;
- Limitation of the oxygen concentration;
- Increase of carbon dioxide.

In any case it is recommended that the filter be changed when there is evidence of dust in the incubator and more importantly change of filter with every change of patient..

Do not try to clean, wash or sterilize the micro-filter in order to re-use it.

To change the micro-filter:

- Take off (pulling it) the special "cover" using the provided indentation found on the right side of the cover itself;
- Clean it along with the housing and then insert the new micro-filter in the right direction after having written the date of substitution in the space provided on the bottom right of the micro-filter itself, which must be easily visible from the outside.

N.B. Ginevri does not assume any responsibility for eventual malfunctions of the equipment or damage to people and or other devices resulting from the use of other types of micro-filter.

## 6.4 CONTROL PANEL

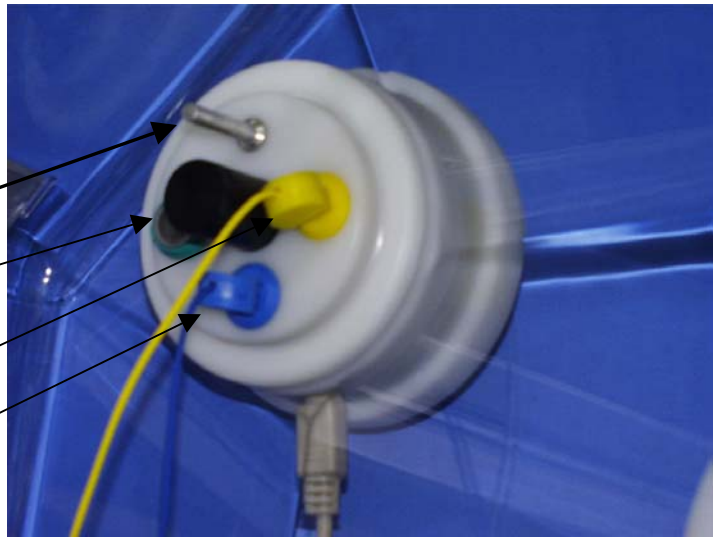
The control panel can be put in or taken out of its housing in the base of the incubator simply by unscrewing the rounded chrome knobs.

**ATTENTION** Before taking the control panel out, always turn the incubator off and leave it to cool down for at least 30 minutes and disconnect the power lead. In this way, you avoid any electrical or thermal problem for the operator.

## 6.5 DETECTING PROBES GROUP ASSEMBLY

Insert the probe group in the hood through the special housing and fix it with the threaded ring.

The skin temperature probes have to be connected internally to the probe group by the special connectors paying attention to the connectors' colours (as indicated in the figure).



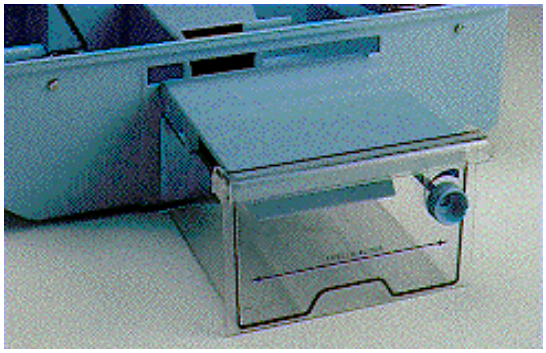
Air temperature probe

Humidity probe

Skin temperature probe SKIN 1

Skin temperature probe SKIN 2

## 6.6 HUMIDIFICATION SYSTEM

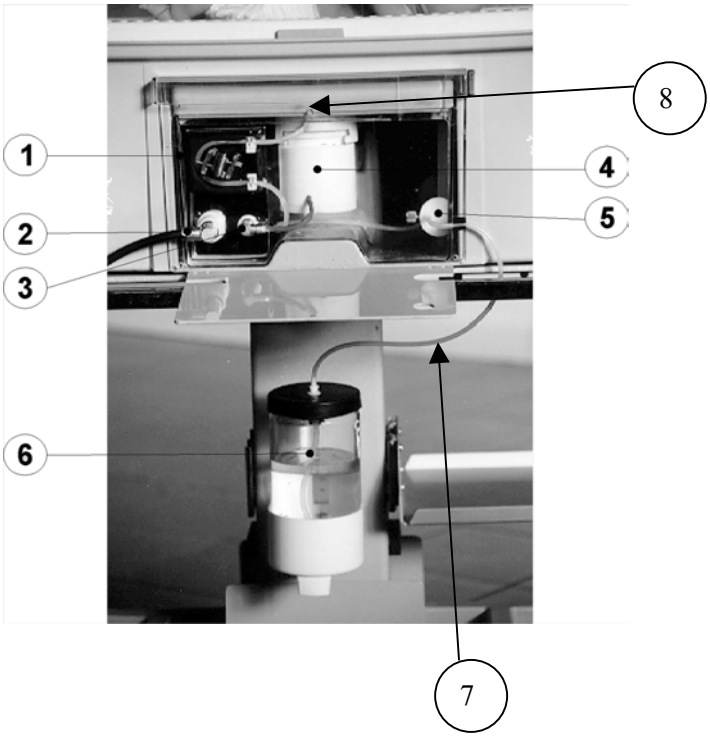


**OGB PolyTrend** Incubators can accommodate:

- **standard humidifier** that consists of a water reservoir, made of pressure fusion polycarbonate, located in the base of the incubator (see pages 36 and 37);

## 6.7 Servo-Steam humidifier

which comes with the same water reservoir as the standard humidifier and therefore is interchangeable with it.
With respect to the standard version it has some modifications which make it completely separate from and isolates the vapour from the environment reserved for the patient. An internal wall serves this purpose.
Given that with the ServoSteam, the humidity comes from the evaporation of some drops of water which come from outside, in this version the water reservoir is **exclusively** used to only hold components to create, according to the necessity, the **sterile vapour** necessary inside the environment of the incubator.
The complex consists of:




1) Peristaltic Pump, to take in and measure out the droplets of water in the evaporator,

2) Connecting wire to the control panel;

3) Connecting wire for the evaporator heater with a right angle connector;

4) Evaporator;

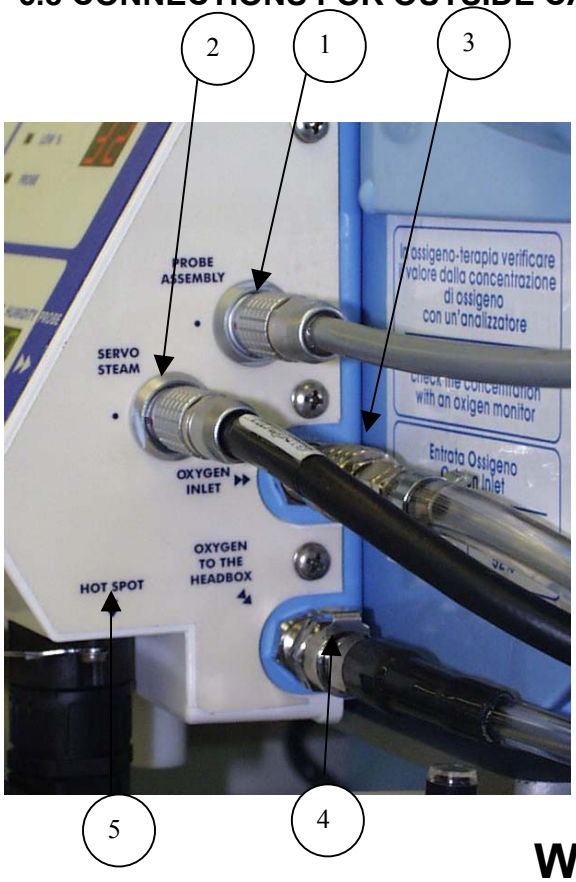
5) Support for water supply tube;

6) External water reservoir container (it is located on the outside of the incubator);

7) Tube in silastic, calibrated to carry the water from the external water reservoir to the to the droplet maker of the evaporator (8) passing through the peristaltic pump (1); ;

8) Connector for the Evaporator's water droplet maker.

## 6.8 CONNECTIONS FOR OUTSIDE CABLES




**RIGHT SIDE VIEW OF THE CONTROL PANEL**

1) **Probe Assembly** Connector and connecting cable to the probe group

2) **Servo-Steam** Connector and connecting cable to the **Servo-Steam** humidifier;;

3) **Oxygen Inlet** Connector connecting the incubator to the medical oxygen supply;

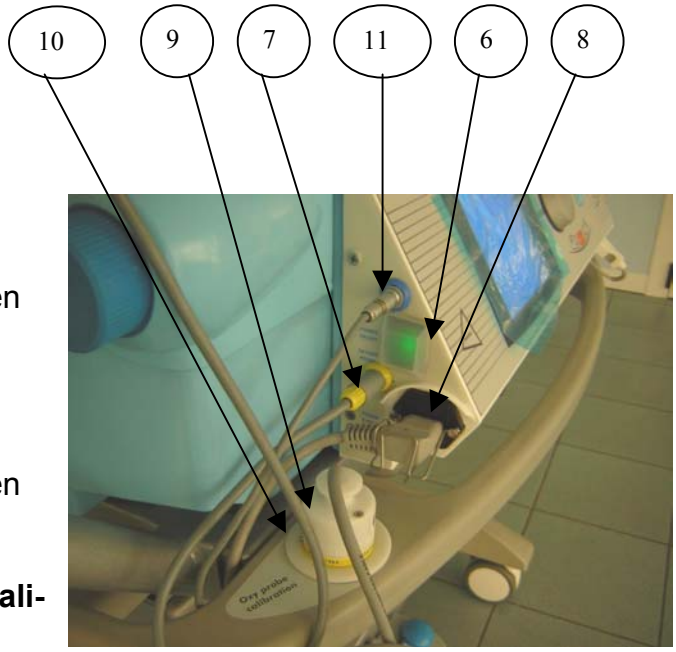
4) **Oxygen to the Head box** Connector and connecting tube to the Head box for oxygen therapy;

5) **Hot Spot** Connector for connection to supplementary radiant heat;

# WARNING

**The attachment and detachment of the connectors must always be done when the incubator is turned off..**

RIGHT SIDE VIEW OF THE CONTROL PANEL




6) ) Power On/Off switch

7) **Oxygen probe**, Connector of the oxygen concentration reading sensory probe;

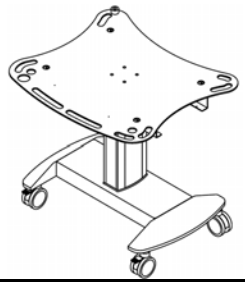
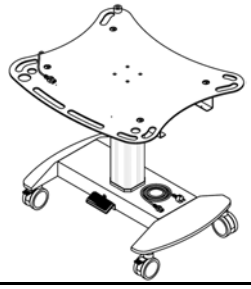
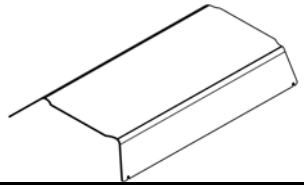
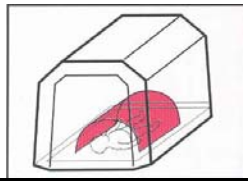
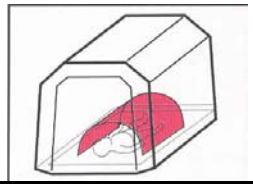
8) **Power supply**, electrical power plug

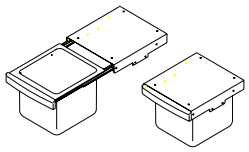
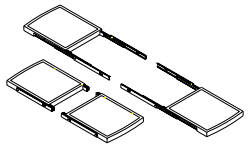
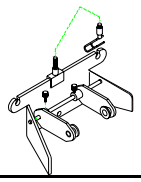
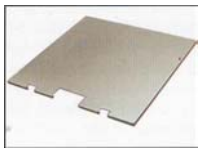
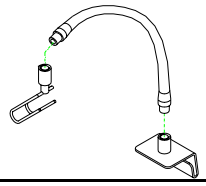
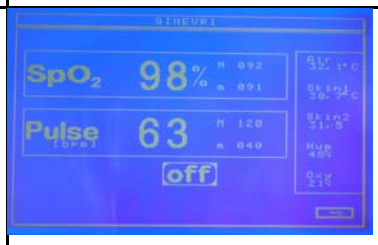
9) **Sensor** probe for reading the oxygen concentration in the air;

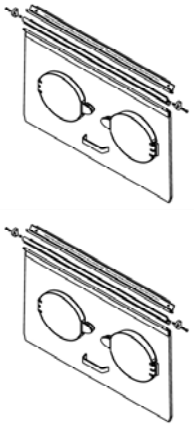
10) **Support** for the oxygen sensor and its **calibration**.

11) Remote Monitor Cable Connector (optional)

# 7. ACCESSORIES

| Ref. | Code | Description/Immagines | |
|---|---|---|---|
| 1 | 11400A70 | TROLLEY WITH FIXED CENTRAL COLUMN |  |
| 2 | 11410A70 | TROLLEY WITH HEIGHT ADJUSTABLE CENTRAL COLUMN |  |
| 3 | 12393A70 | DOUBLE HOOD |  |
| 4 | 559 | HEADBOX MICRO-CLIMATE 30x20x13 |  |
| 5 | 589 | HEADBOX MICRO-CLIMATE 35X25X15 |  |
| 6 | 1521 | IV POLE COMPLEX | |
| 7 | 6922 | IV POLE STANDARD | |
| 8 | 722 | BED BASIN | |

| | | | |
|---|---|---|---|
| **9** | **11401A70** | **SERVICE DRAWERS** |  |
| **10** | **11405A70** | **SERVICE WORK TRAYS** |  |
| **11** | **7647** | **NEONATAL HEAD IMMOBILIZER** |  |
| **12** | **1693** | **X-RAY TRAY** |  |
| **13** | **5740** | **JOINTED SHELF** | |
| **14** | **10712A70** | **MOVEABLE INTUBATION SUPPORT** |  |
| **15** | **12093A70** | **SUPPLEMENTARY POLYTREND MONITOR** | |
| **16** | **12030A70** | **INTEGRATED BILLA** | |
| **17** | **11459A70** | **PULSE OXYMETER** |   |

| | | | |
|---|---|---|---|
| **18** | **11912A70** | **The hood with a silent hinge**<br>**Pack of 2**<br><br>*(Note: This accessory can be mounted only in factory.)* |  |

## 7.1 INTEGRATED BILLA SCALES (12030A70)-(OPTIONAL)

### 7.1.1. General

The Billa is a precision electronic scale designed and created by Ginevri specifically to be used inside the PolyTrend incubator. The design philosophy which has guided it creation is always the same:

- High sophistication and technology internally
- Simplicity of use and maintenance of the exterior.

The scales come integrated inside the PolyTrend incubator and is totally controlled and managed from the its own control panel by using the encoder.

The scales are made up of a weighing plate, which can be integrated into the incubator's patient holder tray.
The micro-processor acquires the data furnished by the charge cells and taking advantage of sophisticated measurement algorithms and rejection of electrical disturbances, permitting an accurate and repeatable reading with a precision level superior to that found with normal weighing systems.

In addition the micro-processor facilitates the implementation of a series of functions which simplify the weighing of the newborn.
Simply by pressing on a button it is possible to see the weight variations of the newborn during the day, calculate the difference between net and gross weight, and show the weight changes. All of this with a precision greater than ±2 grammes.

### 7.1.2 Warnings

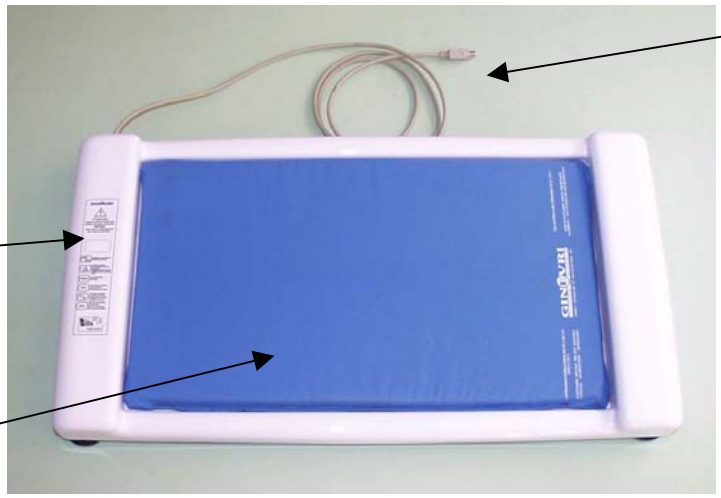
*The Billa* is a precise measuring instrument, and therefore it is necessari to adopt a series of small precautions to be able to make maximum use of its sophisticated characteristics.

- The scales' maximum weight is 10 kg, loads higher than this can damage it.
- Keep the weight tray flat and free to move.
- Tubes, covers, and other accessories must totally rest on the patient tray.
- Always zero the scales before placing the baby on the scales, otherwise the scales will show the weight of everything resting on the tray.
- After verifying an error it could be necessary to RESET the system. To do this turn off and disconnect the scales plug from the sensor probe assembly and re-connect it after making sure that the scales are flat and do not have any weight on them.

### 7.1.3 Billa Description

The Billa Electronic Scale is made up of a single piece described below, to be used it must be connected to a Ginevri PolyTrend incubator.

1. Tray
2. Mattress
3. Connection for the central unit




**ATTENTION**

To avoid irreparably damaging the weighing unit you must absolutely avoid the following conditions:
- presence on the tray of a total weight higher than 10 kg;
- let the power cells go to a negative charge. For example moving the unit by holding it by the baby holder tray (1.4-1) instead of by the flat aluminium bottom where the feet supports are fixed.

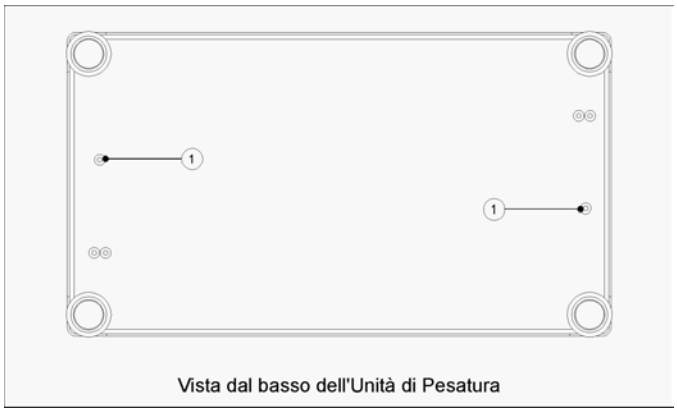
Before turning the scales on make sure that the two safety screws located on the underside have been removed. (See paragraph 2.1).

### 7.1.4 Preparation of the Scales

Take the scales out of their packing case.

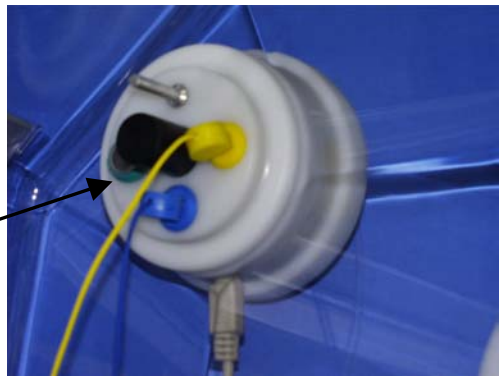
Completely unscrew the two screw found under the Weighing Unit (2.1-1) which safeguard the sophisticated Load Cells during transport. Place the safety screws with the packing case and keep them for any future transport and /or move. In managing the weighing unit always hold it by the aluminium underside.

This precaution is necessary to avoid any possible damage to the Cell. Position of the Weighing Unit flat inside the incubator or where it is required to use the apparatus and make sure that the baby carrying tray is free to move, if not the weight measurements taken will be affected by errors



Vista dal basso dell'Unità di Pesatura

Follow the operations described above, connect the weighing unit and the incubators sensor probe assembly as in the Figure.




### 7.1.5. Switching On

Remove all superfluous weight from the scales plate and turn the incubator on.

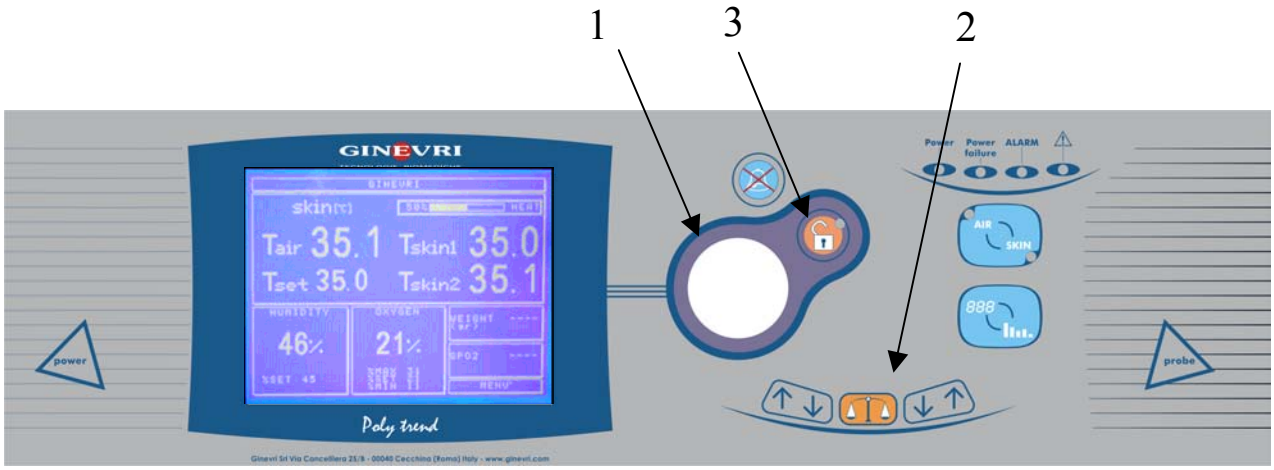
During the switch on phase the scales calibration will be carried out. In this phase in the scales display a zero weight and some dashes under the writing WEIGHT will be shown. When the calibration is finished the writing LOCKED will appear under the word WEIGHT. At this point the scales are ready to weigh.

### 7.1.6 Base Functions

Use of the Billa Electronic Scales is very simple.
To weigh a baby place it on the tray and read the weight on the display.
During cleaning operations it is recommended to disconnect the scales from the incubator.

### 7.1.7 Using the scales

To use the scales you need to use the PolyTrend incubator’s control panel as shown in the Figure.




1) The encoder allow the selection of the desired function for managing the incubator. To use the encoder you are referred to the PolyTrend incubator’s manual.

2) The Scales button calls up the scales display and permits you to return to the incubator’s principle display screen after the use the of the scales has been finished.

3) The Block key blocks and unblocks the use of the encoder to avoid accidental or non-essential settings.

To access the “Scales Display” simply press the Scales button or with the encoder on the principle display select “Return” and then “Scale” menu. If the encoder block light comes on you need to press the Encoder Block key before being able to use the encoder.

### 7.1.8 Description of the Scale Display Screen of the PolyTrend Incubator

The "Scales Display Screen" on the display will appear as in the figure.

The display screen is made up of the following frames with the words WEIGHT, DELTA, STORE and command panels in the bottom of the display ZERO, STORE, gr/lb, RETURN.

**WEIGHT**

The current weight will be shown in the upper frame next to the word WEIGHT.
*If in the weight level reading window dashes (---) appear this indicates that there are problems due to the connection between the weighing unit and the incubator's sensor probe assembly; or there is a malfunciton. In this event contact technical service assistance*

The writing LOCKED under the writing WEIGHT indicates that the scales have been calibrated and that the current weight is correct. When the weight changes by more than 5 grammes from the previous weight reading the scales will take a new weight reading and write dashes (---) in the area under the word WEIGHT. When the weight becomes stable again the work LOCKED will appear again.

**DELTA**

In the DELTA frame the difference between the actual weight on the scales and weight the last memorized with the STORE command will be appear.

**STORE**

In the STORE frame the last weight memorized using the STORE command will be shown.

### 7.1.9 Command descriptions

**ZERO COMMAND**

Selecting the ZERO field using the encoder and press the encoder to re-define the zero of the plate, use this command only when the plate is empty, otherwise it is possibile to use the STORE command to memorize the weight of items of interest to be memorized

**WARNING!** To effect the ZERO the weight needs to be stable and the work LOCKED needs to be present under the word WEIGHT. In addition, the scales must be flat and no inclination must be displayed on the video on the scales. If the inclination indicates that it is not calibrated carry out the incline meter's calibration which is explained later in this manual.

**STORE COMMAND**
The Billa electronic scales is equipped with a memory which permits the registration of the measured level readings and to put them into correlation with successive value readings. In this way it is possibile to see increases and decreases in the newborn’s weight (with respect to the base memorized weight) being able to rapidly return to the current reading display.
Select the STORE frame using the encoder and press the encoder to memorize the weight shown in the WEIGHT frame.
This command can be used to memorie the weights of things of interest to be memorized, for example before the newborn’s first feeling to be able to read in the DELTA frame the difference between the actual reading and that previously memorized.

**THE gr/lb COMMAND**
Selecting the **gr/lb** command using the encoder and pressing the encoder changes the measurement unit used on the scales display. The means that it is possible to see the weight in either grammes or pounds and ounces.

**THE RETURN COMMAND**
Selecting the Return frame with the arrow using the encoder and pressing the encoder will transfer onto the incubator’s principle display screen.

### 7.1.10. Advanced Functions

In addition to the normal functions of the scales previously described the Billa electronic scales is equipped with two important functions:

- Visualisation of the weight variation over time using the trends;
- Visualisation of inclination .

### 7.1.11 Visualization of weight variations

The integration of the scales into the PolyTrend incubator permits sophisticated checks on the baby's weight variations during the baby recovery. If you connect the scale to the incubator it will be possible to display the baby's weight of the last week. This can help the physician to better evalute the growth of the baby. To display the weight trend you have to select through the encoder the **"weight trend"** selection in the encoder the **"trend"** page, as you can see at page 18 of this manual. Once selected the following screen will appear.

It is possible to see the weight Trends of the last 3, 6, 12, 24, 48 hours or even to the last 7 days. The time resolution used in the visualisation is the last one that has been set. To change the time resolution turn the encoder to select the desired time interval and then press the encoder, the page will be re-designated with the newly selected setting.

### 7.1.12 Visualization of the scale's inclination

The integrated balance is able to weigh the baby even in inclined positions showning on the screen the real weight. In this case the degrees of inclination will be displayed on the screen to the side that the scales have been raised by showning the measurment in the number of degrees and an indication bar. When the scales weigh in this inclined mode the precision is affected by ± 5 gr. In any case it is not possible to zero the position when not horizontal.

### 7.1.13 Zero inclination

In this case on the screen the will be shown the scales position even when horizontal, the calibration from zero inclination should be re-done. To do this put the scales plate flat and on the incubator's principle menu display, select Menu and press the encoder, then select SETTINGS and press the encoder, select TECHNICAL and press the encoder and finally turn the encoder to select the command "0 Incl." and press the encoder. To exit from the screen select RETURN and press the encoder. Check that on the scale's display screen the inclination has returned to zero. This setting will be memorized even when the machine has been turned off until the zero-ing procedure has been carried out again.

## 7.2 PULSE OXYMETER (11459A70)-(OPTIONAL)

Integrated into the PolyTrend incubator it is possible to have a pulse oxymeter **INSTALLED ESCLUSIVELY IN THE FACTORY.**
The pulse oxymeter sensor probe connector is positioned on the front panel in the bottom right as shown in Figure 1. The sensor probe is made up of two parts, one re-usable and one "disposable"(single use).
The activation of the pulse oxymeter is positioned on "ON" command found in the diagram dedicated to Figure 4.
Before starting the monitoring of SpO2 and of the Pulse Rate:

- Set the relevant alarms
- Check that the values shown are stabilized.
- Activate the alarms by switching the control onto "ON" as described below.

On the principle display screen it is possible to see the $SpO_2$ level and the Pulse Rate measured in the frame in the bottom right (see Figure 2). To access the display that manages the pulse oxymeter's alarms from the principle menu, you need to select the Menu field using the encoder and access the next display screen (Figure 3) clicking on it. Select the "$SpO_2$" and click again.
The display screen will appear as in Figure 4.
By turning the encoder it is possible to select the fields for:
MAX $SpO_2$ alarm, MIN $SpO_2$ Alarm, MAX Pulse Rate Alarm, MIN Pulse Rate Alarm, Deactivation of the Alarms.

By clicking on one of the selected fields and turning the encoder it is possible to change the alarm settings confirming the choice by pressing on the encoder.
The MAX $SpO_2$ alarm can be disabled by setting it to over 100%.
The maximum possible setting level for the MIN $SpO_2$ alarm is the level set for the MAX alarm.
The MAX Pulse Rate alarm can be set to up to256bpm.
The maximum possible setting level for the MIN Pulse Rate alarms s the level set for the MAX alarm.
The field below (ON/OFF) indicates the activation or less of the alarms related to the pulse oxymeter.
From the Return field it is possible to go back to the main display screen.

ON the right the vital parameters and management of the incubator will always be shown and updated..
Positioning the sensor probe incorrectly, lack of connection, going over the limits set for $SpO_2$ and Pulse Rate will be signalled in the area reserved for Alarms with precise captions that indicate in unmistakable manner the alarm which has been activated, that alarm is in any case also acoustic.
When the alarms are activated due to a disconnection or an incorrect positioning of the sensor probe no numerical values will be shown, only dashes.
In the case of perfusion or too much light warnings will be shown on the $SpO_2$ display screen.

## 7.3 - HOT SPOT RADIANT HEATER-(7533)-(optional)

The **OGB PolyTrend** can be equipped with the **Hot Spot** system (optional).
It is a next application for supplementary warming of the little patient.
It is used in specially designed right angle of the incubator hood.
The **Hot Spot (1)** is a radiant infra-red heat source controlled using the SKIN operating system of the incubator allowing for the maintenance of a constant skin temperature, pre-set, of the newborn even with both of the incubator's door panels open.

**INSTALLATION AND FUNCTIONING**

To install the HOT SPOT on the hood work as follows:

- Remove the plastic **angle cover** of the hood, unscrewing the two rounded chrome fixing bolts.
- Insert the HOT SPOT in place of the before mentioned cover, previously taken out, and attach it with the previously mentioned bolts;
- Make sure, by using the specially provided clips, that the connection cable is connected to the incubator's control panel.
- Unscrew the screw cap of the ***Hot Spot*** plug located under the right angle of the control panel.
- Insert the connector wire into the plug indicated above and screw in the fixing ring nut to the connector itself.
- Affix the Hot Spot Control Module onto the specially designed support attached to the front right "leg" of the trolley;
- Press the On switch of the Control Module to turn the HOT SPOT on.

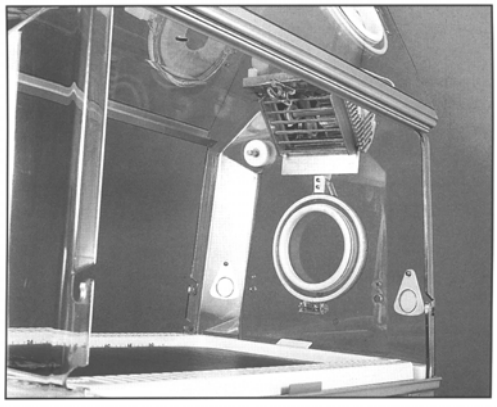
WARNINGS

**The Hot Spot turns on:**

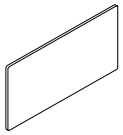
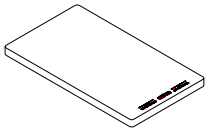
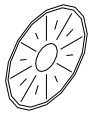
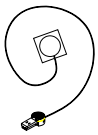
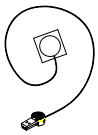
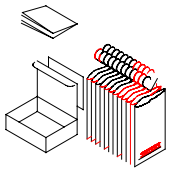
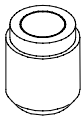
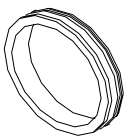
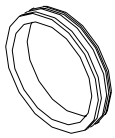
- **Only when the PolyTrend is operating in Skin Mode Control;**
- **Only when the oxygen concentration in the hood is at 21%. Therefore, the oxygen concentration sensor probe which gives permission for the activation of the radiant heat must :**
  - **Have been calibrated (see page 20);**
  - **Be inserted into the appropriate support inside the hood;**
  - **Show an oxygen concentration reading less than 22%.**

## The operations described above must be followed to have the permission to turn on the HOT SPOT.

**An acoustic alarm will indicate that the system is active.**
**The alarm is self re-setting and re-actives automatically every 10 seconds. Satisfying the precautions indicated above, the HOT SPOT will automatically, through the incubator's servo-control, give the newborn a healthy and pleasant heat bringing and maintaining the little patient's temperature to the pre-set temperature level even with the two incubator door panels completely open.**



## 8. SPARE PARTS AND CONSUMMABLES

| Ref. | Code | Description/Image | | Qty |
|---|---|---|---|---|
| 1 | 11130A72 | FILTER AIR |  | Pack of 12 |
| 2 | 434 | MATTRESS |  | Each |
| 3 | 11725A73 | SLEEVE FOR PORTHOLE |  | Pack of 12 |
| 4 | 11730A73 | THERMOMETRIC AL NEONATAL SENSOR PROBE (BLUE) |  | Pack of 6 |
| 5 | 11730G73 | PERIPHERAL NEONATAL SENSOR PROBE (YELLOW) |  | Pack of 6 |
| 6 | 565 | "GEL REFLECT" SENSOR PROBE FIXATIVE |  | Pack of 24 |
| 7 | 1711A | REBRIL DETERGENT POWDER (Pack of 2 Kg.) |  | Each |
| 8 | 11721A73 | RUBBER SEAL FOR DOORS WITH OVAL PORTHOLES |  | Pack of 6 |
| 9 | 12029A73 | RUBBER SEAL FOR THE HOOD (ROUND OLES) |  | Pack of 6 |
| 10 | 10267A73 | OXYGEN SENSOR | | Each |

# 9. APPARATUS' SPECIFIC FUNCTIONS AND APPLICATIONS

The **OGB POLYTREND incubator** is an apparatus which has be studied, designed and manufactured to create and maintain the "ideal" micro-climate necessary for newborns and to allow for the widest and most complete range of medical assistance.

The device puts at the operator's disposition a series of functions designed to create and maintain the micro-climate most adapted to the patient's clinical state. The functions are the following:

1. Air Thermo-regulation air with a setting range between 20°C – 37°C , and in special cases with particular programming between 37°C and 39°C.
2. Skin Thermo-regulation with a setting range between 25°C – 37°C , and in special cases with particular programming between 37°C and 39°C.
3. Humidity Servo-control with a setting range between 10%-90%.
4. Oxygen Servo-control with a setting range between 21%-65% in the hood, or 21%-90% when the oxygen output is limited only to the baby area (head box).

# 10. CLEANING THE APPARATUS

Open the hood, folding the front door upwards;
Take the patient tray out operating as described in page 13 for insertion;
Loosen the handle, rounded chrome, which holds the side vent panels and extract them.
Lift the hood from the base, lifting it using the palms of the hands on the upper internal surfaces of the hood itself (See photo page 13).
Place the now removed hood onto a flat surface.

**DUST REMOVAL**

Dust the hood with a clean soft cloth.

**HEATING UNIT**

Disconnect the power supply of the heating unit before cleaning it.
The heating unit is attached to the control panel and, therefore, to extract it is necessary to take the control panel itself out by working on the four chrome rounded fixing bolts (see photo page 15).
The heating element can be cleaned (also by bathing it) with a sanitizing liquid.
In this phase, it is necessary to take particular care to avoid having the liquid get into yhe control panel where all the electrical components are installed.

**WARNING**

**When it is necessary to take the control panel out of the incubator base, take care because the heating element could be fairly or even extremely hot.**
**Before carrying out the operation mentioned above, the incubator must have been turned off for at least 30 minutes beforehand.**

# 11. PROGRAMMED AND PREVENTIVE MAINTENANCE

All electro-medical devices must be maintained regularly, as for the normative law (CEI 1276 G).
The aim of preventive and programmed maintenance is to minimise the need of faults repairing and to obtain:

- Correct functioning;
- Safety for the patient, the operator and the surrounding environment;
- Maximum availability of the device.

Preventive maintenance consists in controls performed by the operator and periodical maintenance. Written programs should be defined regarding every kind of device, based on laws, technical standards and suggestions of the manufacturer. These programs must include controls performed by the operators and periodical maintenance.

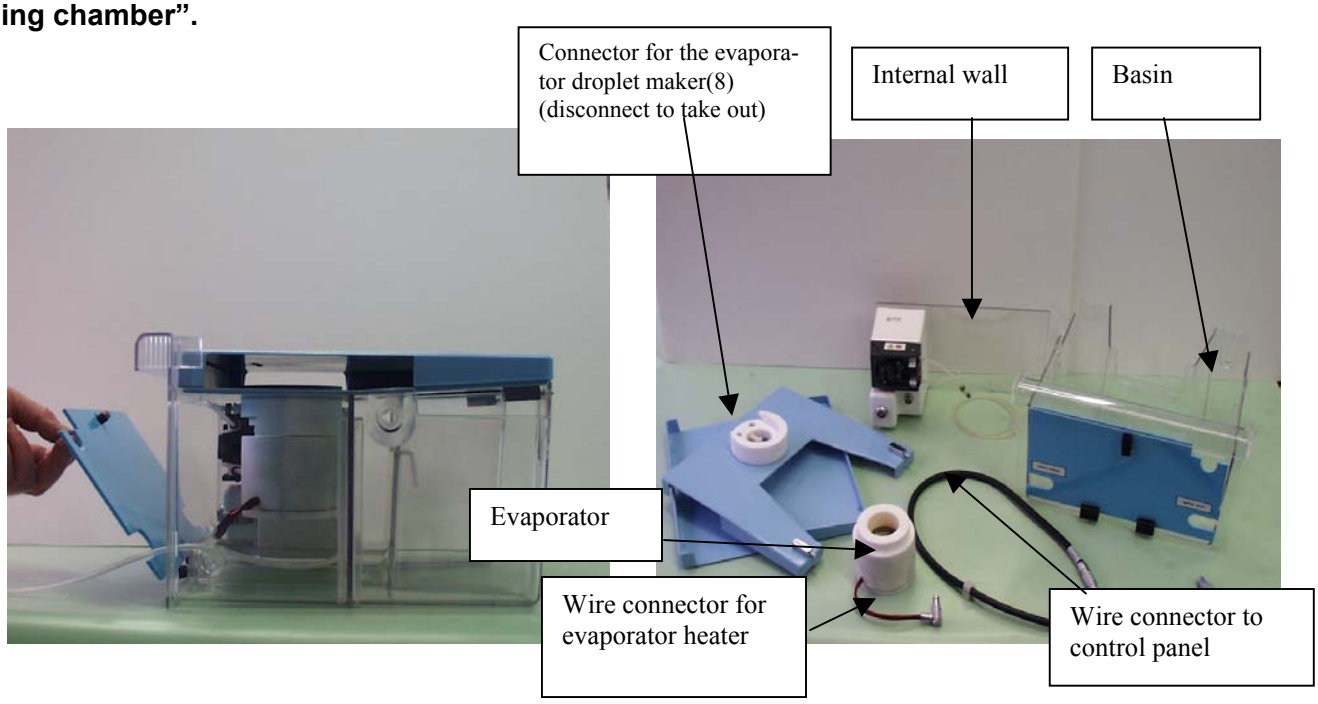
## 11.1 ELECTRICAL SAFETY PARAMETERS CHECK.

Carry out a dispersion and isolation test every year.

## *11.2 METHOD OF USE, FUNCTIONING AND MAINTENANCE*

- **Insert the water reservoir used inside the Servo-Steam humidifier into the appropriate location space found on the base bottom; Inserire la vaschetta contenente il sistema di umidificazione Servo-Steam nell'apposito vano posto sul retro del basamento;**
- **Connect the water reservoir to the incubator's control panel with the connecting wire (2). This wire must be connected to the connector found on the right side of the control panel and labelled <u>Servo-steam</u>.**
- Insert the water container in its holder fixed to the trolley and connect the water supply tube (7);
- Connect the silastic tube (7) to the droplet maker (8) passing the previously mentioned silastic tube (7) through the peristaltic pump and support (5).

**In order to prevent the formation of calcium deposits in the evaporation chamber, we suggest the use of distilled water. However, it is still important to check the heating chamber of the evaporator (4) at least every week if you use normal water. So, to verify the condition of the heating chamber itself for the formation of chalk. This can be eliminated (melted) with a bit of VIAKAL or with a liquid made for that purpose.**
**To take the evaporator out (4) you only need to: disconnect the connecter supplied for that use at angle (3), pulling on it and extract the evaporator (4) towards the outside.**
**On the bottom of the evaporator the "heating chamber" is easily visible and it will show the formation of chalk as a white covering. As the body of the evaporator (4) is made of teflon and is isolated from the heat it can, therefore, be touched during operation. However, the previously mentioned "heating chamber" which is made of metal and works at 135°C can not be touched before it has been able to cool down (approx. 30 minutes).**
**ATTENTION: The Servo-Steam is activated only when the temperature of the "heating chamber" (evaporator) is working properly, i.e. 135°C. A temperature which is reached in approximately 3-4 minutes and therefore to determine the time necessary for pre-heating of the incubator it is enough to follow the time to reach working temperature of the "heating chamber".**


Connector for the evaporator droplet maker(8) (disconnect to take out)
Internal wall
Basin
Evaporator
Wire connector for evaporator heater
Wire connector to control panel

## 11.3 MAINTENANCE MICRO-FILTER

The micro-filter has a filtering capacity of less than 5 μm.
Frequent substitution is recommended and, in any case, it is advisable to do it for every patient.
Do not try to clean, wash or sterilise the micro-filter in order to re-use it.

## WARNING

**A dirty micro-filter means:**

- **Contamination of the air in the interior of the incubator;**
- **Limitation of the quantity of air in circulation;**
- **Limitation of the oxygen concentration;**
- **Increase in carbon dioxide;**

**Before installing a new micro-filter clean the filter holder assembly.**

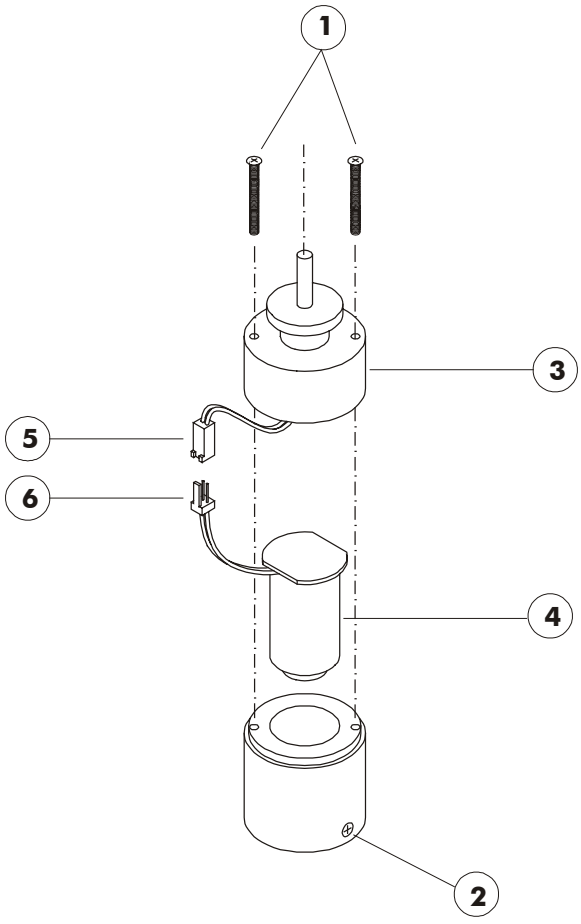
**N.B. Ginevri does not assume any responsibility for eventual malfunctions of the apparatus or damage to persons and/or equipment deriving from the use of other types of micro-filter.**

## *11.4 SENSOR SUBSTITUTION*

The oxygen sensor(4), which is a galvanic cell battery, therefore has a limited life even if it is not utilized.
Even if stored, the duration/lifespan is not unlimited; it is therefore advised to limit the time kept in storage to the minimum absolutely necessary.
To substitute the sensor:

- Dismantle the sensor holder by unscrewing the two screws (1);
- Disconnect the connector (5) (6);
- Loosen sensor holding screw (2);
- extract the sensor (4) and substitute it with a new one.

The duration/lifespan of the sensor, which generally lasts for many months, varies with the variation of the oxygen concentration readings taken: the higher the concentration the less the duration.

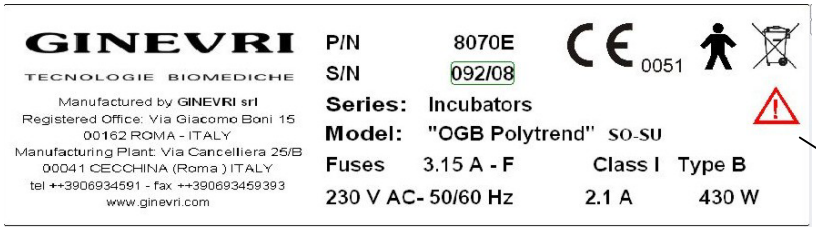


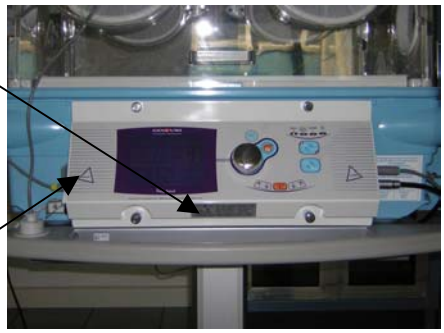
# 12. ELECTRO-MAGNETIC INTERFERENCE AND OTHER INTERFERENCE

All safety measures have been adopted for the OGB PolyTrend in relation to possible electro-magnetic interference in accordance with the current Standards.

# 13. LABEL/TAG AND WARNINGS

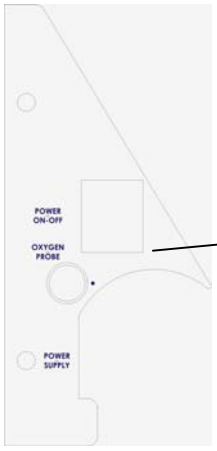
Equipment Identification Label (cod:11523A25):

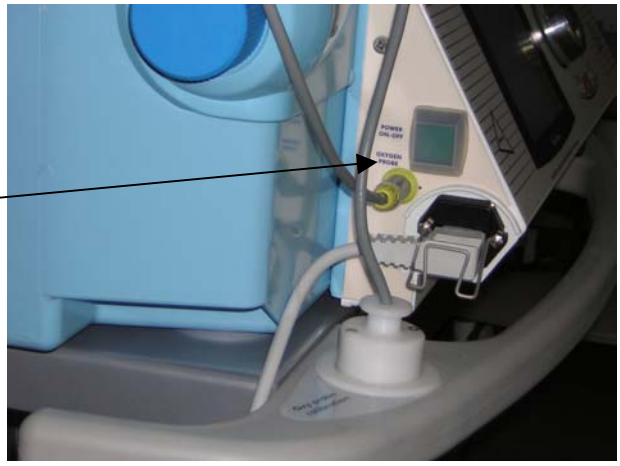


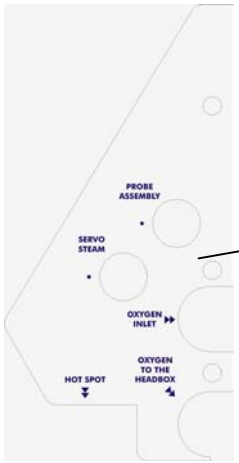
Control Panel OGB poly trend (cod:11876A26):

Left side panel label(code:10663A25):



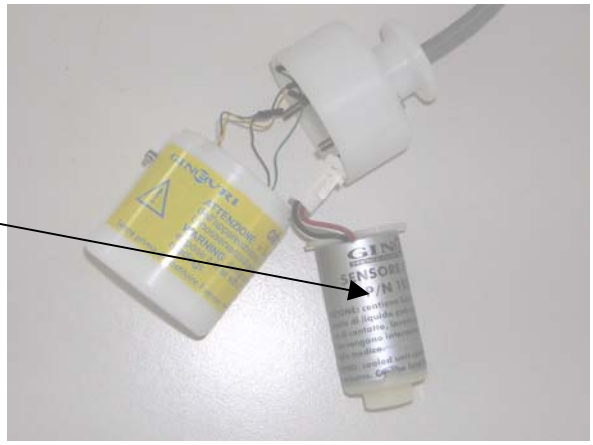



Right Side panel label(code:10664A25):

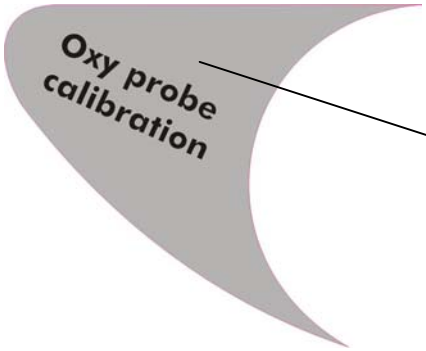


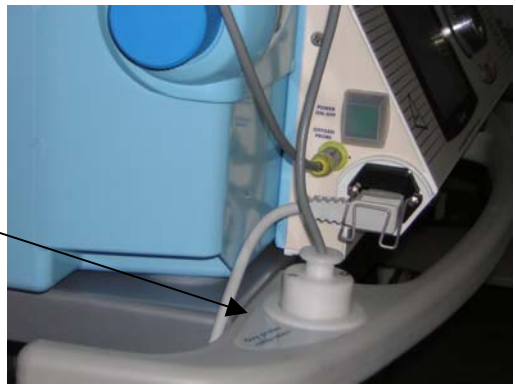
Oxygen sensor label (code:10268A25):

GINEVRI
TECNOLOGIE BIOMEDICHE
SENSORE OSSIGENO
P/N 10267A30
ATTENZIONE: contiene liquido caustico. Una fuoriuscita di liquido può causare lesioni alla pelle. In caso di contatto, lavare per 15 minuti con acqua: qualora vengano interessati gli occhi, ricorrere al consiglio medico.
WARNING: sealed unit contains caustic. Causes severe burns. Can be fatal if swallowed.



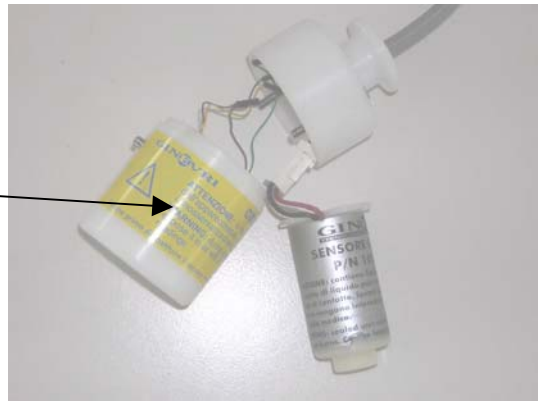
Oxygen Calibration support label on the trolley (code:11894A25):



Oxygen probe label (code:10396A25):

GINEVRI
OXYGEN PROBE for Poly trend
ATTENZIONE: in fase di calibrazione, posizionare la sonda all'esterno dell'apparecchiatura in un ambiente con concentrazione di $O_2$ al 21%. L'inosservanza di questa procedura può causare false letture.
WARNING: during calibration, position the probe outside the apparatus and expose it in air with 21% $O_2$ concentration. Failure to do so may cause wrong readings.
Svitare prima di sostituire il sensore
Unscrew before replacing the sensor

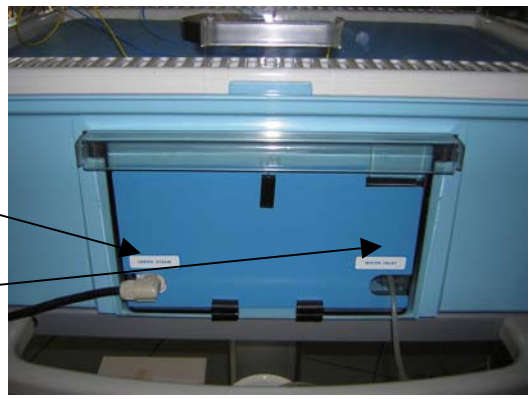


Oxygen label on the base (code:10428A25):

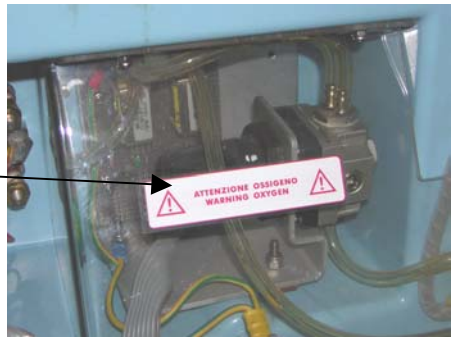
In ossigeno-terapia verificare il valore della concentrazione di ossigeno con un'analizzatore
When oxigen is supplied check the concentration with an oxigen monitor
Entrata Ossigeno
Oxigen Inlet
Fino al Up to 31%
Fino al Up to 52%

Servo-steam probe label (code:10660A25):

Water inlet mini-label (code:10661A25):

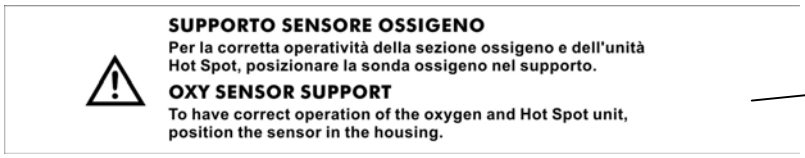


Oxygen Warning label (cod:10662A25):

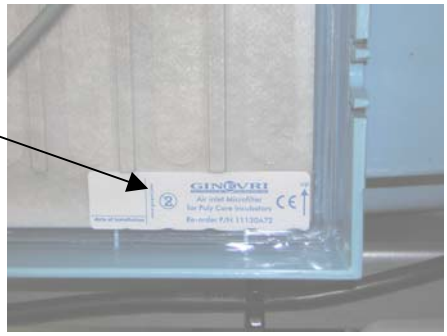



Distilled water label (cod:10665A25):

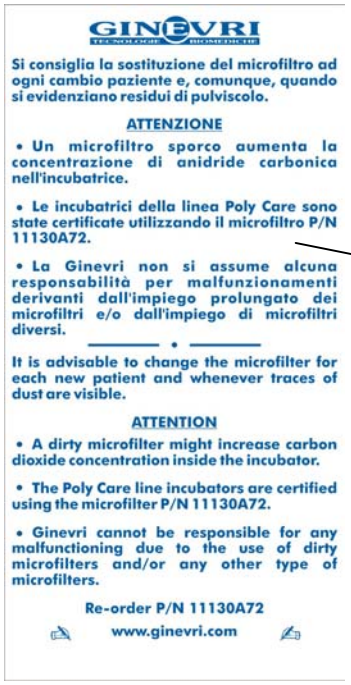
Oxygen support label on the hood (cod:11159A25):

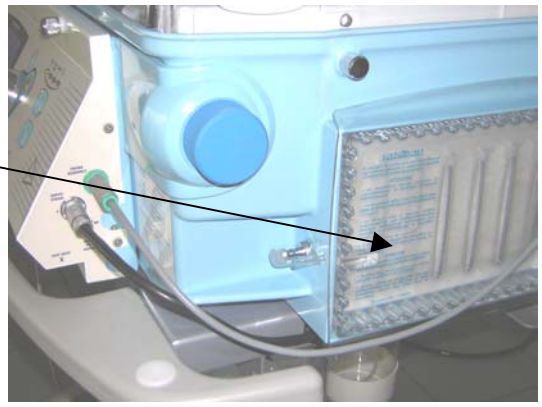

SUPPORTO SENSORE OSSIGENO
Per la corretta operatività della sezione ossigeno e dell'unità Hot Spot, posizionare la sonda ossigeno nel supporto.
OXY SENSOR SUPPORT
To have correct operation of the oxygen and Hot Spot unit, position the sensor in the housing.

New OGB filter label (code:11372A25):



OGB filterholder label (code:11373A25):


GINEVRI
TECNOLOGIE BIOMEDICHE
Si consiglia la sostituzione del microfiltro ad ogni cambio paziente e, comunque, quando si evidenziano residui di pulviscolo.
ATTENZIONE
• Un microfiltro sporco aumenta la concentrazione di anidride carbonica nell'incubatrice.
• Le incubatrici della linea Poly Care sono state certificate utilizzando il microfiltro P/N 11130A72.
• La Ginevri non si assume alcuna responsabilità per malfunzionamenti derivanti dall'impiego prolungato dei microfiltri e/o dall'impiego di microfiltri diversi.
It is advisable to change the microfilter for each new patient and whenever traces of dust are visible.
ATTENTION
• A dirty microfilter might increase carbon dioxide concentration inside the incubator.
• The Poly Care line incubators are certified using the microfilter P/N 11130A72.
• Ginevri cannot be responsible for any malfunctioning due to the use of dirty microfilters and/or any other type of microfilters.
Re-order P/N 11130A72
www.ginevri.com



# 14. STANDARDS

**The OGB PolyTrend IS BUILT ACCORDING TO THE FOLLOWING STANDARDS:**

| | | |
|---|---|---|
| IEC | 601.1 | (CEI 62.5) |
| IEC | 601.2.19 | |
| EN | 55011 | |
| EN | 61000-4-2 | |
| EN | 61000-4-3 | |
| EN | 61000-4-4 | |
| EN | 61000-4-5 | |
| EN | 61000-4-11 | |

MEDICAL DEVICE 93/42/CEE
CLASS IIb

UNI EN ISO 9000:2000 – CERTIFIED QUALITY SYSTEM BY IQNET – No. CERT –IT-37100
UNI CEI ISO 13485 – PARTICULAR REQUIREMENTS FOR MEDICAL DEVICES

CE 0051

# 15. ENTRY AND EXIT SIGNAL PORTS

There are no entry or exit signal ports.

# 16. CLEANING, DISINFECTION, AND STERILIZATION OF THE PARTS IN CONTACT WITH THE PATIENT

## MICRO-FILTER

The micro-filter has a filtering capacity of less than 5 µm.
It is recommended to change it regularly and in any case it is good practice to change it for every patient.
Do not try to clean, wash or sterilize the micro-filter to re-use it.

## WARNING

**A dirty micro-filter means:**

- **Contamination of the air around the incubator;**
- **Limitation of the quantity of air in circulation;**
- **Limitation of the oxygen concentration;**
- **Increase in carbon dioxide;**

**Before installing a new micro-filter clean the filter holder assembly.**

**N.B. Ginevri does not assume any responsibility for any eventual malfunctioning of the apparatus or damage to individuals or objects which result from the use of another type of micro-filter.**

## CLEANING AND STERILIZATION

All **OGB PolyTrend** components can be easily dismantled by hand for maintenance, cleaning and sterilization without the need for additional tools.
REBRIL (p/n 1711) is the cleaning detergent which we recommend and can be used to clean any component.
A special alkaline solution can stop the build-up of calcium deposits without corroding the plastic or metal materials.
**The components are not dangerous for the operators.**
**Do not use cleaning substances which are abrasive or strongly alkaline.**
**Do not scrape the surface with glass cleaning rubbers, blades, razors or other sharp utensils.**
**Do not clean the incubator when it is hot.**

## DISMANTLING

Open upwards the front door of the hood;
Take the patient tray out as described in page 13 to insert it.
Loosen the bolts, rounded and chrome-plated, which hold the side holding bars and take it out.
Lift the hood from the base, lift it with the palms of the hands placed on the interior walls of the hood itself (see photo pg. 13).
Set the removed hood onto a flat surface.

## DUST REMOVAL

Dust the hood with a soft clean cloth.

## HEATING UNIT

Before cleaning disconnect the heating unit from the power supply.
**The heating unit is supporting the control panel and therefore, in order to take it out it is necessary to remove the panel itself pressing on the four rounded chrome fixing screw bolts(see photo pg 15).**
**The heating element can be cleaned (washing it) with a liquid sterilizing substance. In this phase, it is necessary to take extra-special care in order to avoid that any liquids get into the control panel where all the electrical components are installed.**

**ATTENTION**

**When it is necessary to take the control panel out of the base, be careful because the heating element could be very hot.**

**Before carrying out the above procedures, the incubator must have been switched off for at least 30 minutes.**

WASHING

**R E B R I L**
**SOLUBLE DETERGENT FOR THE TREATMENT OF:**
**WASHING – DISINFECTION – STERILIZATION**
**OF MEDICAL EQUIPMENT AND PARTS**
**(ART. 1711)**

- It is a detergent in powder form, slightly alkaline, and easily soluble in water;
- It has the D.L.G. Quality Mark and corresponds to the exact washing and disinfection needs required in various fields, also industrial and food production;
- It has the advantage of having a combined detergent action – chloro-active;
- Does not effect or mark in the least plastic materials, rubber, or light metals (tin, aluminium and related alloys) and stainless steel;
- It is protective of the user's skin;
- Softens the water and impedes calcium lime deposits.
- Block the formation of deposits on the specially treated surfaces.
- **Made up of:** **Active Chlorine gr. 2.4;**
  **Inorganic sodium salts** (silicates, carbonates, phosphates) **gr. 96;**
  **Surface active Anionics** (alkaline, sulphates, sodiums) **gr. 1,6**.

METHOD OF USE

- Completely dissolve the required quantity of detergent in water, 50gm in 10litres of normal water, at an ambient temperature or not above 25°C;
- Dismantle the various parts to be washed and sterilized;
- Carry out a pre-wash of these parts with lots of water at ambient temperature;
- Carry out the washing with the prepared solution of detergent/sterilizer. The duration of this operation will be regulated by necessity, keeping in mind that the slower and more thorough the washing, the more efficient the combined actions of cleaning and sanitizer will be;
- Rinse very well with lots of normal temperature water.

To get the best result carefully follow the instructions above doing the washing with a very soft cloth or with a sponge or with a shammy cloth; and in particular when treating the transparent surfaces, like the hood, the humidifier, etc..

# ATTENTION

**Whatever your intention to use other detergents different from Our REBRIL, remember that solutions containing Surface active, clorexedina, lauryl oxide and whatever else useful for washing and disinfecting the hands, can cause irreversible damage to the Polycarbonate (Lexan) parts of the incubator and to the patients. Therefore exclusively use detergent agents known for their compatibility with polycarbonate( Lexan ).**

| PROBLEMS ENCOUNTERED | POSSIBILE CAUSES | SOLUTIONS |
|---|---|---|
| - Lack of power supply. Alarm not active | - Power supply not turned on. | - Press down the POWER switch. |
| - Lack of Power Supply Alarm is active. | - The protective fuse has blown.<br>- The power supply cable has been unplugged. | - Change the fuse.<br>- Verify the power cable is correctly plugged in. |
| - MAX TEMP Alarm is active. | - Outside source of heat<br>- Air circulation system is blocked. | - Take precautions to eliminate the source of external heat.<br>- Remove the obstruction. |
| - Fan Failure Alarm is activated. | - Breakdown of the fan and/or of the motor. | - Change the fan and/or the motor. |
| - LOW TEMP Alarm is activated. | - Door(s) left open..<br>- SKIN sensor probe not well attached to the skin(only in SKIN MODE). | - Close all the doors.<br>- Check the positioning of the SKIN sensor probe. |
| - Skin probe sensor alarm is activated. | - The Skin probe connector is not correctly attached. | - Verify that the Skin probe connection is correct. |
| - PROBE CABLE DISCONNECTED Alarm is activated. | - Probe assembly connection is not properly installed.. | - Check the probe assembly connection is properly done. |
| - Low humidity percentage. | - The water level is low in the humidifier. | - Check the water level. |
| - Low oxygen percentage. | - Calibration not carried out correctly. | - Repeat the calibration procedure. |
| - OXY PROBE DISCONNECTED Alarm is activated. | - Oxygen probe connection is not properly installed. | - Check the correctness of the oxygen probe installation. |

## 17. POWER SUPPLY WITH ADDITIONAL POWER SUPPLY SOURCES

There are no other power supplies with additional electrical sources.

## 18. BATTERY REMOVAL

There are no removal batteries.

## 19. RE-CHARGEABLE BATTERIES

There are no re-chargeable batteries.

## 20. APPARATUS WITH SPECIAL POWER SUPPLY OR BATTERY RE-CHARGER

There are no apparatus with special power supply or battery re-charger.

## 21.ECO-COMPATIBLE RECALL and DISPOSAL

This apparatus is an electro-medical device and therefore does not come under the scope of the RoHs Directive.
Conforming to the Directive 2002/96/CE, known as the RAEE Directive, and to the implemented Italian legislation , our electronic and electrical apparatus are marked with the symbol shown below, provided for by the CEI EN 50419 Standard.
This apparatus must not be disposed of with domestic rubbish/garbage.
For RECALL of rejected equipment, please contact our Customer Assistance Dept (see the first pages of this manual). The apparatus, at the end of its useful life, must be disposed of according to the Standards in force at that time.

# 22. TECHNICAL CHARACTERISTICS

| | |
|---|---|
| - **INCUBATOR BODY** | A Single piece of injection moulded polycarbonate |
| - **ELECTRICAL POWER SUPPLY** | 220v 50/60 hz |
| - **ELECTRICAL CONSUMPTION** | 430w (570w with hot spot) |
| - **SAFETY CLASS (IEC 601.1/CEI 62.5)** | 1st |
| - **CATEGORY (IEC 601.1/CEI 62.5)** | B |
| - **MEDICAL DEVICE CLASS (93/42/CEE)** | II B |
| - **EARTHING CURRENT** | 70 μA |
| - **ELECTRICAL PROTECTION** | 2 Fuses 5x20mm 3.15Amp F |
| - **POWER SUPPLY FAILURE ALARM** | Included, complete with an internal rechargeable accumulator |
| - **AIR TEMPERATURE INDICATOR** | 0.1°C Resolution, 0.6°C Maximum Error |
| - **SKIN TEMPERATURE INDICATOR** | 0.1°C Resolution, 0.3°C Maximum Error |
| - **O2 CONCENTRATION INDICATOR** | 1% Resolution |
| - **HI/LOW O2 CONCENTRATION ALARM INDICATOR THRESHOLD ALARM** | 1% Resolution (optional) |
| - **HUMIDITY INDICATOR INSIDE THE HOOD** | 1% Resolution, 10% Maximum Error |
| - **TEMPERATURE SETTINGS LIMITS** | From 20°C to 39°C AIR, from 25°C to 39°C SKIN |
| - **MAXIMUM TEMPERATURE ALARM** | Audio visual Alarm automatically deactivates the heating when internal hood temperature is higher than 38°C. |
| - **HUMIDITY CONTROL** | From 10% to 90% |
| - **IDEAL ROOM TEMPERATURE** | From 21°C to 26°C |
| - **AMBIENT HUMIDITY VARIATION** | From 35% to 90% |
| - **STORAGE TEMPERATURE** | From -10°C to +50°C |
| - **HOOD INTERNAL NOISE LEVEL** | Less than 45dB |
| - **VENTILATION** | 36 Lt/min multi-directional |
| **MAXIMUM CO2 CONCENTRATION (MEASURED WITH TESTS DEFINED IN IEC 601 - 2 – 19 CEI 62.22)** | ≤ 1 per 1000 |
| - **MAXIMUM CARRYING CAPACITY OF THE PATIENT BED** | 10kg. |
| - **DIMENSIONS:**<br>**-INCUBATOR……**<br>**-HEIGHT FIXED TROLLEY (11400A70)……**<br>**-HEIGHT ADJUSTABLE TROLLEY (11410A70)……** | <br>83x65x69 cm (W,D,H,) approx.<br>89x73x72 cm (W,D,H,) approx.<br>89x73x72 cm (W,D,H,) approx. |
| - **WEIGHT:**<br>**-INCUBATOR……**<br>**-HEIGHT FIXED TROLLEY (11400A70)……**<br>**-HEIGHT ADJUSTABLE TROLLEY (11410A70)……** | <br>37 kg approx.<br>41 kg approx.<br>55 kg approx. |